

LONG-TERM ADJUSTMENT AND REIMPLANTATION SURGERY IN PATIENTS  
WITH IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

Karen E. Jakub

A dissertation submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the School of Nursing

Chapel Hill  
2012

Approved by:

Deborah Mayer PhD, RN  
AOCN, FAAN

John Paul Mounsey BSc  
BMCh, PhD, MRCP,  
FACC

Linda Beeber PhD, RN,  
CS

Margaret Sandelowski  
PhD, RN, FAAN

Noreen Esposito EdD,  
WHNP, FNP

© 2012  
Karen Jakub  
ALL RIGHTS RESERVED

## ABSTRACT

KAREN JAKUB: Long-Term Adjustment and Reimplantation Surgery in Patients with  
Implantable Cardioverter Defibrillators  
(Under the direction of Dr. Margarete Sandelowski)

Implantable cardioverter defibrillators (ICD) are the standard of care for individuals with life-threatening cardiac arrhythmias. These devices treat arrhythmias by rapidly pacing or shocking the heart into a normal rhythm. Within the first year of implantation patients make physical, psychological, and social adjustments to living with a device. Yet, although patients are living with these devices for many years, the long-term consequences of implantation are only beginning to be explored. One aspect of living for many years with an ICD is the experience of defibrillator replacement. Patients are required to have a new device implanted every 4-7 years due to battery depletion. In addition, as ICD components age, surgery may be needed to repair or replace worn parts. Accordingly, the purpose of this study was to examine the long-term physical, psychological, and social consequences of living with an ICD and the experience of recurrent surgery for patients with ICDs. The focus of the study was to identify distinctive differences in this experience among various ages, and between men and women.

Twenty-three participants were recruited from a major regional hospital in North Carolina through the ICD device clinic. Ethnographic methods of participant observation, interviews, and medical record reviews were used to collect data over a one-year period. Data were analyzed and interpreted using a with-in case and cross-case method, focusing on concepts generated from a variety of gender, chronic illness, and age-related theories. The

findings concerning long-term adjustment to living with an ICD were characterized by both differences and similarities according to sex and age. Men exhibited more bravado than women and were more likely to engage in risk-taking behaviors. Women remained engaged in caring behaviors following implantation and surrounded themselves with other women as their support network. Young women were also concerned about childbearing once they had an ICD. Both men and women were concerned about reimplantations; the risks, technology reliability, financial strain, scarring, and continued follow-up for years to come. Their initial implantation caused concern and angst that diminished over time, thereby moving the focus away from the ICD to other aspects of their lives.

## ACKNOWLEDGMENTS

First, I would like to thank my family for their support and sacrifice during this endeavor. My gratitude is especially heartfelt toward my husband, my mentor and friend, who has always been patient and supportive as I pursued my dream. Also to my father, whose endearing words spoken during the last days of his life gave me inspiration and strength to finish this journey.

I extended my gratitude to the faculty at the University of North Carolina at Chapel Hill, who gave me an amazing education and a desire to continue the advancement of the science of nursing. I would like to recognize and thank the members of my dissertation committee for their contributions to this research study and dissertation process. I am especially grateful and honored to have worked with Dr. Margarete Sandelowski though these many years. Her inspiration and mentorship, encouragement, and understanding kept me motivated and on track.

I would like to thank the physicians, nurses, and support staff of the Electrophysiology Department at the North Carolina Memorial Hospital of the University of North Carolina Healthcare System for their contribution to this study. My special thanks and gratitude goes to the nurses in the device clinic, Marybeth Beyer and Audrey Chacon, who were welcoming and worked collaboratively through the recruitment process. Their willingness to share their expertise in ICD patient care and management was enlightening.

I would also like to thank the ICD recipients who chose to share their stories with me. Their candor and generosity was sincerely appreciated. My hope is that I was able to capture their experiences in a way that may benefit their care and the care of other ICD recipients in the future.

Lastly, I would like to acknowledge the sources of financial support during my doctoral studies: the UNC School of Nursing Interventions to Prevent and Manage Chronic Illness Institutional National Research Service Award from the National Institute of Nursing Research, 2005-2007 (Grant Number T32 NP007091, 1996-2011); the Glaxo Fellowship Fund Scholarship, 2007, and the Elizabeth Scott Carrington Scholarship Award, 2008.

## TABLE OF CONTENTS

LIST OF TABLES.....	ix
LIST OF FIGURES.....	x
Chapter	
I.    INTRODUCTION.....	1
II.   BACKGROUND AND SIGNIFICANCE.....	5
III.  METHODS AND THEORY.....	23
IV.   FINDINGS: Gender, Age, and the Experience of Technology.....	37
Men.....	38
Men, Age, and Development.....	41
Women.....	43
Women, Age, and Development.....	46
Men and Women.....	47
ICD Perceptions.....	47
Social Support.....	49
Financial Concerns.....	51
Decisions about Reimplantation.....	52
V.    DISCUSSION.....	54
Clinical Implications.....	59

Research Indications.....	61
Conclusions.....	63
TABLES.....	66
FIGURES.....	76
APPENDIX.....	80
Appendix A: Institutional Review Board Approval.....	80
REFERENCES.....	82



## LIST OF TABLES

### Table

1. Sample Characteristics
2. Reimplantation Observation Guide
3. Device Check Observation Guide
4. Interview Guide
5. Medical Record Data Extraction Guide
6. Contact Summary Form

## LIST OF FIGURES

### Figure

1. Implantable Cardioverter Defibrillator with Lead Placement
2. Antitachycardia Pacing for Arrhythmia Termination
3. ICD Computer Programmer
4. Stored ICD Electrogram



## **Chapter I.**

### **Introduction to the Study**

Implantable cardioverter defibrillators (ICDs) are the standard of care for individuals surviving sudden cardiac death and life-threatening ventricular arrhythmias (Antiarrhythmics versus Implantable Defibrillators [AVID] Investigators, 1997). The ICD delivers a shock to the heart, thereby interrupting the ventricular arrhythmia and allowing a normal heart rhythm to resume. With more than 230,000 implanted annually in the United States (Wilkoff et al., 2008), ICDs are credited with decreasing the risk of mortality 30-54% in patients with high-risk cardiac conditions.

ICD implantation began in the late 1980s with restricted indications for implantation and limited technological capabilities. These devices were used only for secondary prevention, that is, only patients who had survived a previous cardiac arrest or had witnessed ventricular arrhythmias were candidates for implantation. More recently, the results of clinical trials have led to the expanded use of ICDs for primary prevention, that is, to prevent cardiac arrest in patients at risk of an arrhythmic event (Moss et al., 1996; Moss et al., 2002). These expanded indications for implantation have increased the number of patients with ICDs.

Within the first year of implantation, patients have to make physical, psychological, and social adjustments to the device (Carroll, Hamilton, & Kenney, 2002; Dunbar, 2005). This adjustment occurs over time and usually results in a satisfactory quality of life for many patients. Yet, although patients are now living with these devices for many years, researchers

are only beginning to focus on the long-term consequences of implantation (Carroll & Hamilton, 2008; Flemme et al., 2005). One aspect of ICD technology still to be explored is the patient's experience of defibrillator replacement. Patients with ICDs are required to have a new device every 4-7 years due to battery depletion. In addition, as ICD components age, additional surgery may be needed to repair or replace damaged or worn parts. Little is known about the experience of frequent recurrent surgery for ICD replacement.

Accordingly, the purposes of the study reported here were to examine the (a) long-term (i.e. > 4 years post-initial implant) physical, psychological, and social consequences of living with an ICD and the (b) experience of recurrent surgery for patients with ICDs. Ethnographic methods (Spradley, 1979, 1980) including participant observation, interviews, and review of medical records, were used to answer the following research questions:

1. How does the experience of ICD replacement compare to initial placement?
2. What alterations, if any, in their lives do patients with ICDs attribute to the device?
3. Are there any distinctive differences in experience between female and male ICD patients, among young (18-40), middle (40-65), and older (>65) adult patients, and between patients receiving ICDs for primary versus secondary prevention?
4. What happens during the reimplantation procedure that may have an influence on patients' experiences?
5. What happens during ICD interrogation and lead-testing procedures that may have an influence on patients' experiences?

Patients have to make several psychological and social adjustments following their initial implantation. Those at higher risk of poor psychosocial outcomes tend to be younger, have less social support, and are women (Dunbar, 2005). Also at high risk are patients who have experienced a high number of ICD shocks and other comorbid health conditions. The long-term psychosocial adjustment to living with an ICD has only begun to be studied. Because reimplantation surgery and ICD interrogations reoccur throughout a patient's life, these procedures may result in varied and unpredictable changes in psychological and social adjustments.

The number of people with ICDs has increased over the past 25 years due, in part, to expanded indications for implantation. Yet, experiential differences between those receiving an ICD for prophylaxis and those who have had previous arrhythmic events have not been examined. Patients receiving ICDs for primary prevention tend to be younger and at risk from structural heart disease, or congenital or genetic defects (Sherrid & Daubert, 2008). The possibility exists that patients could have a device that never delivers therapy, yet they will still have to endure multiple reimplantation procedures, years of monitoring, and remain at risk for complications as a result of the technology.

Long-term ICD management, including reimplantation surgeries, may span decades of a patient's life, thereby crossing over several adult developmental periods. Psychological and social stages associated with particular age-related cohorts may influence the experience of living with an ICD. Changes in the experience through time and patients' perceptions of that experience may be different while engaged in those various stages of life. Examining recurrent implantation surgery and the subsequent long-term experience of ICDs thus provides an opportunity to gain knowledge that may be applicable to patients with different

types of implantable devices that must also be replaced (e.g., pacemakers, heart valves, prosthetic joints, cochlear implants). The intent of surgically implanted technologies is to ameliorate health or prolong life, yet the technology itself can present unique challenges. As in the case of ICD reimplantation, surgical procedures are necessary because of technological limitations of the device, as opposed to illness or disease. The frequency of ICD replacement is typically greater than with most other technologies at 4-7 years, presenting a unique opportunity to examine the recurring replacement experience.

Ultimately, the importance of the knowledge gained about long-term ICD patients will be key to improving the nursing care of these patients. Nurses in hospitals may encounter ICD patients at any time and in any setting. Not only is it important for nurses to be knowledgeable about the technical aspects of the technology, but also to be aware of the ongoing influences an ICD may have on a patient's life. This knowledge will assist nurses in advising patients of future expectations concerning their ICD. By presenting patients with a realistic view, fears and anxieties may be diminished. In addition, many nurses participate directly in patient care surrounding surgical reimplantation. They practice in device clinics, same-day surgery sites, cardiology units, catheterization or electrophysiology laboratories, and operating rooms. By examining the experience of patients undergoing reimplantation surgery, nurses may gain new insight to develop evidence-based care practices for these patients.

## **Chapter II.**

### **Background and Significance**

Understanding patients' experiences of ICDs requires an understanding of the technology itself: how it functions, and the procedures surrounding maintenance and monitoring of the device. Early devices were large requiring an abdominal insertion site with mesh epicardial defibrillation pads sutured on the outside of the heart. This required major open-chest surgery (thoracotomy) and an extensive recovery period for individuals who were already at high risk because of cardiac disease. This original insertion site and older lead systems may still be in use today. Later ICD models became smaller and lead systems changed, resulting in an implantation procedure that placed the patient at lower risk (Wild et al., 2004).

An ICD system may be a single-chamber device, with one lead in the right ventricle, or a dual-chamber device, with an additional lead placed in the right atrium. The leads are typically inserted into the cephalic or subclavian vein advanced through the superior vena cava and secured in the heart. A similar device, a cardiac resynchronization therapy device (CRT-D), adds an additional lead to treat patients with cardiomyopathy and heart failure. The CRT-D is a programmable defibrillator that shares similar therapy features, programmability, battery life, leads, and surgical implantation techniques with the ICD. In addition to defibrillation capabilities, the additional lead enables the bradycardia pacemaker to pace the right and left ventricles synchronously. Patients with heart failure and cardiomyopathy are



known to benefit from this biventricular pacing by improving cardiac hemodynamics and, thereby, decreasing mortality (Bristow et al., 2004).

Surgery for ICD or CRT-D implantation is performed in cardiac catheterization labs, electrophysiology labs, or operating rooms. The defibrillator's smaller size (approximately 30 cm, 60 g) now allows for implantation in the right or left infraclavicular region of the chest wall, usually in a subfascial pocket (Stevenson et al., 2004, see Figure 2.1). The procedure results in a visual 3-4 inch scar and some bulging at the implantation site because of the size of the ICD. Nurses with specialized training administer medications to maintain sedation throughout the procedure with relatively low complication rates (Pachulski, Adkins, & Mirza, 2001).

### **ICDs Deliver Shocks and Pacing Therapies to Treat Ventricular Arrhythmias**

ICD functions include rhythm detection and discrimination, as well as treatment modes for bradycardia and ventricular tachycardia. Erratic life-threatening heart rhythms, such as ventricular tachycardia, often occur without warning or prodromal symptoms. In some instances, patients experience mild dizziness or palpitations, but the speed of rhythm detection and ICD activation reduces the occurrence of these symptoms. The ICD is able to detect the abnormal rhythm within seconds ( $< 10$ ) and begin a sequence of programmed directives to terminate the rhythm.

Several treatment modalities are possible. A device may be programmed to deliver only high-energy shocks to the myocardium. If one shock fails to terminate the arrhythmia, as many as six successive shocks may follow. A shock sensation has been described by patients as a sudden, unexpected "hit in the chest," or "like a bolt of lightning" (Dunbar, Warner, & Purcell, 1993, p. 497). Some patients have described it as "not as bad as they

thought,” and believe the shock is something they must endure if they want to live (Dickerson, 2002, p. 366). Because of the discomfort associated with high-energy shocks, other treatment modes may be programmed before a high-energy shock is delivered. Known as tiered therapies, ICDs can be programmed to deliver antitachycardia pacing and/or low energy shocks (cardioversion) to stop the ventricular tachycardia (Cannom & Prystowsky, 2004; Gehi, Mehta, & Gomes, 2006). Antitachycardia pacing is a series of short bursts of paced beats programmed to be faster than the ventricular arrhythmia intended to disrupt and terminate the ventricular tachycardia (see Figure 2.2). This therapy is painless and typically undetectable by patients. Cardioversion is delivery of low-energy shocks to the heart and is thought to be less painful than high-energy shocks. Physicians often choose to program combinations of tiered therapy, in which ventricular tachycardia is terminated by a succession of antitachycardia pacing, and low- and high-energy shocks.

### **ICD Management Includes Device Interrogation and Monitoring**

ICD management includes routine follow-up and maintenance with healthcare providers to access cardiac diagnostic information, assess battery life, and evaluate proper technological function. Some of the newest devices now allow patients to have their ICDs interrogated and monitored by remote access through the telephone, however, this technology is only available with a select number of devices (Jung, Rillig, Birkemeyer, Miljak, & Meyerfeldt, 2008). Most are typically evaluated in a physician’s office or a hospital cardiac device clinic every 3-6 months depending on the age of the ICD. Under the physician’s direct or indirect supervision, patients sit or recline as their device is interrogated by a nurse, physician, or ICD company representative (Wilkoff et al., 2008). To interrogate an ICD, a round, solid, or donut-shaped wand is positioned over the ICD or a wireless

connection is made to a manufacturer-specific ICD computer programmer (see Figure 2.3). During this device interrogation, specific measurements are obtained that provide estimates of the remaining battery-life. As the battery begins to show wear, patients unable to have their devices evaluated by phone are required to increase their visits to the device clinic every 3 months.

Also during the device interrogation procedure, past arrhythmic events and ICD therapies are recalled from the memory of the device. The recorded events provide information to healthcare providers of the exact dates, times, type of rhythm, and antitachycardia therapy that had been delivered. Stored, retrievable cardiac electrograms provide a visual display to aid diagnostic determination of the cardiac rhythm and the appropriateness of the delivered therapy (see Figure 2.4). Physicians use this information to evaluate the effectiveness of the prescribed therapies, change pharmacological treatment, and/or make necessary programming changes.

Because some ICD therapies are considered painless (antitachycardia pacing), patients may be unaware of past events and try to determine what, if anything, they did to cause the arrhythmia (Dunbar et al., 1993). In some instances, patients may believe they have experienced a shock, but none is confirmed upon ICD interrogation. This phenomenon is known as phantom shock. Phantom shocks may occur in patients at any time throughout the post-implantation years and is thought to be associated with increased levels of anxiety and depression (Prudente, Reigle, Bourguignon, Haines, & DiMarco, 2006).

The stability and integrity of the lead system is also tested during routine follow-up visits. Lead pacing and shock impedance values are obtained automatically through the programmer and the leads are checked for sensing and pacing capabilities. The procedure to

check these functions requires the technician or nurse use an ICD computer programmer to make changes in the patient's heart rate.

In order to check a lead's ability to sense properly, the operator drops the programmed pacing rate of the ICD below a person's normal heart rate. The ICD programmer then automatically and incrementally changes the sensing parameters until the device no longer detects the person's own intrinsic rate. Patients may not sense changes in their heart rate, but, if their intrinsic rate is very low (i.e., 30-40), it may cause some lightheadedness, dizziness, or unusual sensations. If a patient has no intrinsic rhythm, lead sensing cannot be determined. All leads are checked individually in this manner.

In addition to sensing, all leads are checked for pacing capabilities. To perform this test, the operator increases the pacing rate to be significantly higher than the intrinsic rhythm (i.e., causes the heart to race). The ICD programmer automatically and incrementally drops the strength of the electrical impulse delivered to the pacing electrode of the lead until there is no longer capture of the myocardial tissue. Myocardial capture is a term analogous to a cardiac contraction. During this process, particularly if a person has no intrinsic rhythm, one or several heartbeats may be lost. This often produces an uncomfortable and unusual sensation for the patient. Rapid pacing during the test may also cause an irregular sensation, such as palpitations or flushing. Should any sensing or pacing irregularities exist, changes may be made in the device's programming, or surgery may be required to repair or replace a lead.

## **Long-Term Management of ICDs Includes Recurrent Surgery for Battery Replacements**

An ICD is expected to reach the end of its battery life or elective replacement indicators in  $4.4 \pm 1.5$  years with even fewer years expected for ICDs with rate responsive modes and biventricular pacing capabilities (Hauser et al., 2006). The exact number of years a device will last is variable among manufacturers' brands and from patient to patient. Battery life is dependent on many factors, such as how much it is used (for pacing or defibrillation), programmed voltage pacing parameters, and the size and specifications of the battery (Ellinor, Guy, Ruskin, & McGovern, 2003).

The battery is sealed within the ICD, thus requiring an entirely new device to be implanted. The procedure is typically done as an outpatient/same-day surgery in an electrophysiology laboratory. The surgery consists of removal of the old device and testing the lead(s) for sensing and pacing capabilities. A new ICD is connected to the leads and a test is conducted to assess the ability of the system to defibrillate the heart.

Some patients experience technology-related anxiety when their ICDs reach end-of-life parameters due to programmable alerts. These warning tones signal a patient that a problem exists or that the battery voltage is low (Becker et al., 2004). For example, a tone may be audible once daily or, perhaps, every 4 hours until a patient seeks medical attention, to determine the cause of the alarm. Information about whether these alerts are present is available to healthcare professionals when the ICD is interrogated. The experience may cause considerable anxiety for the patient, especially if they are unaware of the alarm's existence. Additionally, patients have no way of knowing the nature of the problem and may become

fearful of device malfunction or possible impending shock. Yet, experiential data are not available concerning this aspect of ICD implantation.

### **Defibrillation Threshold Testing is Done During Surgery**

Testing the ICDs ability to stop a ventricular arrhythmia is known as defibrillation threshold testing, in which ventricular fibrillation is induced and terminated with a low energy shock. This is done, in part, to determine the lowest amount of energy necessary to stop a patient's ventricular fibrillation and provide information to assist the physician in programming the ICDs shock parameters effectively. This procedure also tests the integrity of the defibrillation lead. If problems are detected (e.g., failure to defibrillate the myocardium, insulation defect/fracture, or pacing/sensing improperly), insertion of new leads may be required. In some instances the original ICD site may have to be abandoned and an entirely new site selected.

This procedure is considered generally “safe and rarely associated with serious complications such as myocardial stunning, cerebral hypoperfusion, intractable VF (ventricular fibrillation), pulseless electrical activity, and death” (Kowalski, Huizar, Kaszala, & Wood, 2008, p. 442). Yet, based on my own clinical experience, many patients struggle with the thought of having their “heart stopped” to test the device. They are fearful that problems will occur and their heart will not return to a normal rhythm. This fear may increase as the patient ages, with each successive implant, and as health begins to decline. Researchers have yet to explore this experience.

### **Surgery is Related to Device or Lead Malfunction or Infection**

More than one third of all reimplantation surgery is related to ICD malfunction, lead failure, or infection (Gepner et al., 2007). Defibrillator malfunction has led to device recalls

with increasing regularity over the past several years. Recalls are issued due to possible electrical malfunction, battery or capacitor malfunction, or other defective physical components of the device. The possibility of a device not functioning properly may add to the anxiety experienced by some patients with ICDs (van den Broek, Denollet, Nyklíček, & van der Voort, 2006). For patients who undergo ICD surgery for recalls, lower quality of life has been associated with the potential for a life-threatening malfunction of the device (Undavia et al., 2008). According to Sears and Conti (2006), there is a “fundamental principal that patients with ICDs must have faith in their devices, or their psychological acceptance of the devices is altered” (p. 565). The security of life-saving therapy and enhanced heart function (in the case of CRTs) are hallmark qualities of the ICD that contribute to patients’ acceptance and adjustment to living with the device. High anxiety levels are reported in individuals receiving these recalls as they face added follow-up care or reimplantation of defective devices (van den Broek et al., 2006).

The longevity of leads varies but researchers examining long-term lead failures have found a steady decline in lead effectiveness over time (Kleemann et al., 2007). After 10 years, the annual rate of lead defects increases to 20%. Reasons for lead failure are insulation breakage, lead (wire) fractures, loss of ventricular capture (with pacing), abnormal lead impedance, and sensing failure. Many of these problems are detected with measurements done during routine ICD follow-up at a physician’s office or at a device clinic. Some lead complications, however, are recognized following delivery of inappropriate shocks caused by the defective lead. In most instances, the defective lead is left in place and a new lead is implanted. In a study of management of ICD lead failures, patients who experienced lead

malfunctions in original leads had “an eight-fold increased risk for recurrent ICD lead problems” in the future (Eckstein et al., 2008, p. 2732).

ICD pocket infection is a serious complication that can lead to sepsis or even death. Secondary implantation or previous surgical revision of an existing ICD increases the risk of infection significantly (Gepner et al., 2007). Device infection carries a mortality rate of 31%-66% if the system is left in place, and an 18% mortality rate if it is removed and combined with antibiotic therapy (Kowalski et al., 2008). There are no data concerning the experiences of patients having the complications of infection and subsequent removal of their life-saving device.

### **Decisions are Made Regarding ICD Non-Replacement**

Decisions regarding non-replacement of an ICD are made based on health status or end-of-life choices. When describing the experience of patients with implantable defibrillators, Dickerson (2002) suggested that individuals reliant on technology are vigilant about the function of their ICDs, particularly when their battery begins to deplete. The need for a replacement becomes a moral dilemma; that is, a decision to replace an ICD means the patient has to choose between life and death. Patients believe they have little choice in the decision to reimplant their ICD because of healthcare professionals’ strong advocacy for technology to save lives whereby “death becomes a symptom to be treated” rather than the end of life (Dickerson, 2002, p. 365).

In some instances, a decision may be made to discontinue ICD therapy by not replacing a battery-deficient device. Yet, the unpredictability of cardiac arrhythmias and the life-sustaining quality of the device makes non-replacement a difficult choice. The risk of future arrhythmic events remains, even if no antitachycardia therapy has been delivered over



the life of the old ICD (Schoenfeld, 2000). Continued surgical re-implantation of an ICD may be questionable when patients are suffering from an irreversible chronic condition. For example, recipients suffering from severe comorbid conditions, such as cancer or severe dementia, may choose to have their ICD deactivated or not have it replaced. In rare circumstances, patients may request removal or refuse replacement of the device due to severe debilitating stress related to multiple shocks or infection, even if it is discouraged by their healthcare providers (Li et al., 1998).

### **Negative Psychological Symptoms Result from ICD Shocks**

ICD shocks contribute to patients' negative psychological symptoms regardless of the number of years since the initial implantation.

**Anxiety and fear.** ICD shocks have been associated with negative psychological symptoms, the most frequent of which are anxiety and fear. Sears, Tordaro, Lewis, Sotile and Conti (1999) reported ICD-related fear and anxiety in 24-88% of patients with ICDs. Patients experience the anxieties and fears of receiving a shock and the possibility of shock failure that could result in sudden death (Burke, 1996; Dickerson, 2005; Dougherty, Benoliel, & Bellin, 2000). Dougherty (1995) compared patients with and without shocks over a 1-year period following implantation. Those without shocks showed a steady decline in anxiety levels while patients who experienced shocks did not demonstrate a reduction in anxiety over that year. Schron et al. (2002) found even one ICD firing in the first year following implantation decreased physical functioning and mental wellbeing.

To examine the long-term effects of shocks on anxiety, Hegel, Griegel, Black, and Goulden (1997) assessed quality of life, anxiety, and depression over a 2-year period in patients who were 2-8 years post-ICD implantation. They found that 40-63% of patients

continued to have increased levels of anxiety over time. Because the study was conducted with patients who had an ICD for several years past their initial implantation, these researchers concluded that remission of negative psychological states was rare, and chronic emotional disturbances were present in patients with ICDs.

In a similar study, Crössmann, Pauli, Dengler, Köhlkamp, and Wiedemann (2007) used repeated measures over a 2.5-year period. Subjects were 3 months to 7 years past their initial implantation, with 63% having incurred at least one shock at some time during that period. These researchers found that anxiety levels were significantly higher in ICD patients than in healthy subjects at a comparable age, with the anxiety levels remaining stable at both measurement points. Yet, they did not find that actual shocks or knowledge of antitachycardia pacing caused an increase in anxiety. This finding is consistent with that of Pauli, Wiedemann, Dengler, Blaumann-Benninghoff, and Köhlkamp (1999) who found that patients did not exhibit increased levels of anxiety from a shock, but that anxiety was attributed to the anticipation of a shock event rather than the shock itself. Carroll and Hamilton (2005) also reported specific anticipatory fears and that ICD patients who had experienced shocks had anxieties related to the fear of pain, loss of control, and feelings of panic should the device shock them again.

**Depression.** In a comprehensive review of the literature, Sears et al. (1999) found that 24-33 % of all ICD recipients experienced depressive symptoms. Symptoms included fatigue, malaise, loss of appetite, insomnia and loss of interest in activities of daily life.

The onset of depression has been associated with actual and perceived shocks (Goodman & Hess, 1999), poor social support, reduced physical functioning, loss of resources (personal and financial), and longevity with an ICD (Luyster, Hughes, Waechter, &

Joseph, 2006). Heller, Ormont, Lidagoster, Sciacca and Steinberg (1998) correlated frequent ICD shocks with depression. Patients reported increased sadness and tiredness following these episodes. Along with depression, patients in this group also reported anxiety. These authors acknowledged that anxiety is often a comorbid condition with depression that may have an effect on cardiac arrhythmias. Hegel et al. (1997) also correlated depression with anxieties of ICD shocks. In this 2-year study, patients exhibited more depressive symptoms during the second year even though they experienced fewer shocks. This relationship between anxiety and depression was explained as an interactive cycle, in which anxieties related to ICD shocks may lead to depression, just as those who are depressed remain anxious about ICD firings.

### **Psychological Outcomes Affect Interpersonal Relationships and Social Situations**

Psychological consequences of living with an ICD affect interpersonal relationships and social situations following ICD implantation. Patients who experience anxiety resulting from defibrillator-related events sometimes avoid physical activity, crowded public places, or social situations (Carroll & Hamilton, 2005). Worrying about shock activity in a public place results in decreased socialization associated with a loss of control and feelings of panic that a person cannot escape surroundings without embarrassment. Physical activity is often curtailed for fear of increasing one's heart rate above the upper-rate limit (heart rate that will initiate ICD therapy) set in the defibrillator. In a study of avoidance behaviors in patients with ICDs, 55% of respondents reported avoidance of places, activities, or objects (such as cellular phones) regardless of actual shock activity within those areas (Lemon, Edelman, & Kirkness, 2004).

Individuals with implanted defibrillators frequently modify social activities and relationships following implantation. Marital relationships are affected as partners of ICD patients become over protective and discourage activities that will cause a shock or sudden death (Sowell, Sears, Walker, Kuhl, & Conti, 2007). Intimacy and sexual behaviors between partners change, based on these same fears, but may adjust with time through experience and communication. Over time, positive feelings of safety, peace of mind, and trust contribute to acceptance of the device. A sense of social support from family and friends was reported to be the greatest source of comfort and strength to individuals with ICDs (Dougherty, Thompson, & Lewis, 2005; Steinke, Gill-Hopple, Valdez, & Wooster, 2005).

### **Gender-Related Factors Influence Adjustment**

Gender-related factors may play a role in adjustment to ICDs. Women may be affected by ICD implantation differently from men. Physiologic differences have been reported following the initial implantation. Women have reported a higher incidence of sleep disturbance and postoperative pain when compared to men (Smith, Dunbar, Valderrama, & Viswanathan, 2006). These sleep difficulties were influenced by a prior incidence of life-threatening ventricular arrhythmias and were significant regardless of age, cardiac disease, or marital status.

Women have also been found to have poorer psychological adjustment. Sowell, Sears, Walker, Kuhl, and Conti (2007) found that women experienced higher levels of shock and death anxiety, as well as a greater number of shocks. Similarly, in a study of the psychosocial adjustment of women across the domains of shock anxiety, death anxiety, and body image, Vazquez et al. (2008) concluded that women under 50 experienced higher rates of these anxieties and greater body image concerns.

Sowell, Kuhl, Sears, Klodell and Conti (2006) reported increased tenderness at the ICD site because of sensitive breast tissue. Movement and weight of the breast tissue also caused added discomfort as scar tissue would pull or possibly tear. Body image concerns include scarring, clothing fit over the device, socializing problems, and worries about sexual activity. Dubin, Batsford, Lewis, and Rosenfeld (1996) also reported greater body image anxieties in women (89%) than men (43%) particularly when wearing revealing clothing such as a bathing suit. Issues related to body image have not been studied empirically in men with implanted devices.

### **Age-Related Factors Influence Adjustment**

Age-related factors may play a role in adjustment to ICDs. Age differences in patients often reflect differences in disease-related conditions (Hamilton & Carroll, 2003). That is, older patients may receive a device for conditions related to coronary artery disease and heart failure, whereas younger recipients may be treated for genetic disorders such as long QT (wave sequence on an EKG) syndrome or hypertrophic cardiomyopathy. Consequently, these younger patients often receive an ICD for primary prevention of an arrhythmia. When comparing young (<65) and old (>65) recipients, Hamilton and Carroll (2003) found that younger patients had higher levels of anxiety. They also had concerns related to exercise and often reduced their physical activity, thereby affecting their overall health perception and quality of life. In comparison, older patients reported decreased physical activity with diminished overall satisfaction with health status following implantation of their ICD. Other researchers have found that younger patients generally continued their employment following implantation, but reported decreased social interaction and a decrease in sexual activity (Dubin et al., 1996).

## **Quality of Life for Long-Term Patients Varies**

Long-term ICD patients adjust to living with their device, but their quality of life can vary based on uncertainty, physical health, and social support. Recently, investigators have begun to examine the long-term effects of living with an ICD. Wallace and colleagues (2002) found that long-term patients can experience declining quality of life that is influenced by ICD shocks, anxiety, low social support, and the number of years since implantation. Participants in this study received an ICD for secondary prevention for ventricular arrhythmias and had an ICD from 1-4 years. These researchers found that as the number of years passed since the initial time of implantation, physical quality of life decreased. These researchers attributed this finding to worsening medical condition rather than age. In addition, low social support, anxiety, and a greater number of shocks were associated with negative mental quality of life. Overall, patients in this study continued to live with moderate levels of depression and some anxiety. This finding is consistent with that of Luyster et al. (2006) who found that higher levels of anxiety and depression were associated with longevity post-implantation. These researchers attributed this, in part, to the loss of social, personal, and material resources that can occur over time for patients with ICDs.

Flemme et al. (2005) examined uncertainty and quality of life in long-term ICD patients who also received their devices for secondary prevention. In this longitudinal study, they assessed recipients between 4-8 years ( $M=6.9$ ) post-implantation. These researchers found that uncertainty had a negative effect on the health and physical functioning aspects of quality of life over time. Yet, uncertainty decreased in long-term patients compared to those early in the post-implantation period and remained somewhat stable. They also found that strong family relationships and support were associated with higher measures of quality of

life. In addition, family-related quality of life was found to decrease over time, but this could not be attributed solely to the ICD and may have been reflective of normal uncertainties associated with family life. These researchers acknowledged that their assessment of uncertainty and quality of life was not done in association with ICD shocks. In fact, approximately one-third of their sample had never received a shock since the time of implantation, and 15 of the 35 participants had never received a shock since the first year following implantation. Because shocks are known to affect psychological wellbeing, the lack of ICD shocks may have contributed to the finding of decreasing uncertainty over time.

Carroll and Hamilton (2008) examined the long-term ICD effects on health status, quality of life, and psychological states from implantation to 4 years post-implantation. They found improvement in negative psychological mood states, such as anxiety, anger, depression, and fatigue, at 6 months that remained stable over the 4-year period. Yet, because there was no control group comparison, it is unclear whether these negative mood states were similar to those in the general population. Recipients did report a perceived decline in physical health and function during that time affecting their quality of life.

## **Summary**

In summary, ICDs have extended lives well beyond the expectations that were once possible when devices were only available for patients who had survived a cardiac arrest. Empirical research has been focused on the many aspects of living with these devices, primarily in the early years with an ICD. The initial concerns were related to the shock experience. Many patients reported negative psychological symptoms, such as anxiety and depression related to ICD shocks. In most cases, however, patients adjusted to living with their ICD and reported a satisfactory quality of life. Yet, because most studies have been

done within 2 years following implantation, it is unclear how this affects patients over many years. In the few studies of long-term ICD patients, they are portrayed as establishing a satisfactory quality of life, but are still subject to higher levels of anxiety and depression. Patient shock experiences and the influence these have on a patient's life over time have not been addressed. For example, physical and psychological responses to a shock may differ with each event, may influence social or interpersonal relationships differently, or remain unchanged. In addition, the sequencing of ICD therapy over time may also have some influence on a patient's wellbeing. Recipients who have endured years of ICD therapy may be influenced differently from those who received a minimal number of shocks. In addition, patients who have been implanted for primary prevention of ventricular tachycardia may never experience a shock but live with the anticipation of one.

A few studies have been conducted to examine the experience of patients with different demographic characteristics. Young recipients may experience greater difficulties in adjusting to an ICD. Yet, it is largely unknown what influences an ICD may have on a recipient as they age. Life situations, emotions, maturity, and physical durability, to name a few, may contribute to a patient's psychological and social wellbeing through time. Differences have been identified between men and women with ICDs. Women experience more sleep disturbances, body image concerns, a higher shock and death anxiety than men following implantation. Yet, the long-term effect is unknown, as are explanations for these differences. Men may also experience body image concerns. For example, unlike women, men do not always cover their chests and may also be affected by the bulging of the device and fit of their clothing. Because most studies were done following the initial implantation,



comparing the long-term experience of men and women may uncover other events that occur when living with an ICD for an extended period of time.

Missing from the empirical literature, and the focus of this study, is the experience of reimplantation surgery. This is a significant event that will reoccur throughout the remainder of a patient's life. Although this surgery is necessary to continue ICD therapy, it can pose risks, complications, and disruptions in the lives of patients and their families. Very little is known about the experience, such as anticipation, preparation, pain differences with each successive implantation, what the patients' perceptions and expectations are regarding ICD defibrillator threshold testing, and the overall experience of the implantation procedure. With the added inconvenience of life-long ICD interrogations, monitoring, and lead testing, this technology affects patients throughout their lives. Therefore, my aim in this study was to gain knowledge of device reimplantation and interrogation procedures as an integral part of the long-term experience of patients with ICDs.

## **Chapter III.**

### **Methods**

Ethnographic methods (Spradley, 1979, 1980) were used to examine the: (a) long-term ( $\geq 4$  years) physical, psychological, and social consequences of living with an ICD; (b) experience of ICD follow-up device interrogations and lead testing; and, the (c) the experience of recurrent surgery for patients with ICDs. Methods included participant observation of ICD patients during pre-operative, operative, and post-operative ICD replacement procedures, and of ICD follow-up and device interrogation procedures; interviews with ICD patients; and medical record review.

Ethnographic studies are conducted to explore practices, behavior, and customs (Spradley, 1980). Such studies vary in size, ranging from very large cultural examination to a more specific focus. Micro-ethnographies narrow a study to a single social situation or problem of interest. Ethnographers seek understanding by directly observing the actions, behaviors, and interactions participants have with others in a natural setting in order to learn about their world.

#### **Setting**

The setting for this study was the Electrophysiology (EP) Department at the North Carolina Memorial Hospital of the University of North Carolina Healthcare System in Chapel Hill, NC. In this department 61 reimplantation procedures were performed in 2010, the year of this study. The racial distribution is unknown. Data were also not retained on primary versus secondary implantation indicators or age. Medical diagnoses included

ischemic heart disease, cardiomyopathy, congestive heart failure, cardiac arrest, and ventricular tachycardia. The majority of replacements were due to battery depletion. Other reasons for reimplantation were ICD upgrades to different ICD models or biventricular devices (CRT-D). Several areas within the EP Department were used for this study, including the pre-procedure holding area, EP labs, and the device clinic both at North Carolina Memorial Hospital and their satellite office at UNC Hospitals Heart & Vascular Center at Meadowmont. The device clinic provides services for approximately 500 device patients (including pacemakers and ICDs).

### **Sample**

A stratified purposeful sampling strategy was used whereby cases are selected that vary on pre-selected parameters (Sandelowski, 1995b). Directed toward including cases representing every combination of these pre-selected parameters, this strategy is useful in capturing the common and unique elements across cases. Pre-selection of patients whose initial implants were for either primary or secondary prevention of ventricular tachycardia proved difficult because of limited documentation of patients' pre-existing conditions. Therefore, this variation could not be part of the selection process. A total of 23 participants were selected who varied on age, sex, and number of reimplantations. The sample consisted of patients undergoing ICD interrogation and lead testing or reimplantation surgery. Reimplantation procedures were done due to battery deletion, lead revisions, ICD upgrades to biventricular ICDs, or device recalls. The length of time participants had an ICD varied from 4-13 years. Eight patients had never experienced any treatment from their devices, while 15 had experienced either antitachycardia pacing or shock therapy to terminate an accelerated heart rhythm. Ten participants had survived a cardiac arrest either in or out of the

hospital prior to having their initial ICD implanted. Details of participant characteristics are displayed in Table 3.1.

### **Data Collection**

The primary modes of data collection were participant observation, ethnographic interviews, and medical record review. Data were collected over a 12-month period. Eighteen participants were observed and interviewed following their ICD clinic appointment. Five women were observed the day of surgery, of whom four were observed and interviewed at their post-operative follow-up visit to the device clinic.

**Observation.** Participant observation techniques can range from fully engaged participation to passive observer. Researchers position themselves in a natural setting with the purpose of observing activities, people, and physical aspects of a situation (Spradley, 1980). For this study, I positioned myself in selected vantage points outside the patient's cubicle in the holding bay or in the rear corner of the EP lab during the implant procedure, resulting in minimal influence and intrusion upon the scene. The foci of my observations were adapted from Spradley's (1980) dimensions of social situations. They included: (a) space, the physical surroundings of the device clinic, holding bay, the EP lab; (b) actors, with the patient at the center of the scene as well as the family, nurse, physician, and ICD company representative; (c) activity, a set of related acts people do (e.g., interrogating the ICD with the programmer, preparing the patient, conducting the surgery); (d) object, the physical things that are present (e.g., medical equipment, monitors, or the implantable device); (e) time, the sequencing that takes place over time (e.g., lead testing, time in holding bay, EP lab, and return to holding bay); (f) goals, what people are trying to accomplish (e.g., when nurses adequately sedate the patient, when technicians/company representatives

interrogate and program the ICD, when defibrillator threshold testing is done); (g) interactions (e.g., what, with whom, and how people are relating to each other); and, (h) feelings, or the emotions felt or expressed by the patient, family, or personnel.

Informal questions were posed to the actors (hospital personnel) in the scene to understand what they were doing (e.g., goals they were attempting to accomplish) or to clarify observed behaviors. In order to minimize my influence in the setting, these questions were asked when the procedure was over.

The ICD patient was at the center of my observations. Five patients were observed the day of their reimplantation surgery. Patients were admitted into the EP holding bay where pre-operative preparation is done. They were moved to the EP lab for their procedure and returned to the holding bay for recovery. Observations took place throughout the day in each of these areas over the entire course of the reimplantation procedure. Two different EP labs were used, each with different characteristics that influenced the flow of the procedures. Observations were aided by the use of an observation guide (see Table 3.2).

Field notes were handwritten throughout the observation period. Descriptive fieldnotes are written to create a portrait of the environment to describe and produce a “sensory image” to be able to understand the social interactions and activities observed (Emerson, Fretz, & Shaw, 1995, p.69). Integrated into these descriptive field notes were notations on the conversational exchanges among patient, family members, and healthcare providers. Direct quotes were written whenever possible but often paraphrasing was necessary due to the speed of the conversation or inability to hear the entire conversation. A final observation was done approximately 10 days to 2 weeks after the reimplantation procedure when these patients went to the device clinic in the hospital to have their incision

checked for healing and possible suture or staple removal. An ICD interrogation and lead testing procedure may or may not have been done by the nurse in the clinic at that time. Field notes were reviewed and amended at the completion of each day in the field to ensure completeness and accuracy, and to optimize descriptive validity (Maxwell, 2002).

Handwritten notes were typed into a word document for analysis.

Sixteen participants were observed as they underwent device interrogation during routinely scheduled follow-up appointments. The procedure lasted approximately 10-15 minutes, unless there were problems pertaining to medications or errant heart rhythms. I positioned myself in an unobtrusive area of the room with minimal participation in the scene. The foci of observations were the same as for patients undergoing reimplantation surgery, but specific to the device clinic. Observations concentrated on the objects (e.g., the ICD computer programmer, monitors) in the setting, and the activities and interactions between the patient with those objects and with the nurse who conducted the device interrogation and lead-testing procedure (see table 3.3). Attention was focused on the patient's non-verbal and verbal communication as they were positioned in the chair, connected to the ICD programmer and monitoring equipment, and as the tests were conducted. Observations in the clinic yielded information on the influence these procedures might have had on patients' ICD experience.

**Ethnographic interviewing.** In ethnographic interviewing, information is sought by posing questions to guide and encourage dialogue about the topic of interest (Spradley, 1979). In this study, interviews provided accounts of reimplantation experiences and adjustment to living with an ICD from the patient's perspective. They also provided data from which comparisons could be made between men and women and selected age groups.

Interviews began with a grand tour question: “Tell me the story of how you came to have an ICD.” Grand-tour questions are designed to allow the participant to speak at length about a topic without interruption. When participants finished their responses, questions were asked to clarify, expand, or focus on specific aspects of what they had already talked about, in addition to aspects of the target experience not already addressed. For example, when a participant replied, “...I know I have to get the surgery done, so I just go do it,” a descriptive question I asked was: “Could you walk me through your day of surgery, starting when you arrived at the hospital?” A variety of question formats were used, including structural and contrast questions. An example of a structural question was, “What do the nurses do in the device clinic to check your ICD?” An example of a contrast question was: “How did this experience differ from your previous experiences of implantation?” An interview guide was used, with questions designed to reflect topics related to the study’s research questions (see Table 3.4).

Of 17 participants observed in the device clinic, 16 were interviewed in a private conference room located in the vicinity of the clinic following their appointment. One participant was interviewed at a local restaurant near the satellite clinic. One participant was interviewed without being observed. The clinic nurses initiated his recruitment during a concurrent interview with another participant. Participants were asked about their experiences of living with an ICD, their thoughts concerning activities and procedures in the device clinic, and their experiences of reimplantation surgery.

For participants followed through surgery, a similar interview was conducted approximately 10 days to 2 weeks after their procedure at the device clinic. The same interview guide was used as with patients observed in the device clinic, but also included

questions about their most recent surgical experience (e.g., pain after surgery or return to normal activities). Participants were asked also to clarify or verify any data or interpretive impressions generated from observations during their reimplantation.

I audio recorded and transcribed the interviews. If the participants began talking about their experiences before or after the recording started, notes were written immediately following the interview session. These data was included with the transcribed audio data.

**Medical record review.** The limited hospital medical record (only information printed for access at the bedside) and device clinic record were reviewed for patients undergoing reimplantation surgery. A guide was used to extract information regarding demographics, diagnosis, time since implantation, the reason for the initial implantation, the number and reason for ICD replacements, frequency of ATP or shocks, and medical history (Table 3.5). If the participant was observed and interviewed at the device clinic, the device clinic record was reviewed. This record contained information about the ICD from the device interrogation printouts and documentation regarding the lead testing performed while in the clinic. Demographic information, medical history, diagnosis, and medication records were also accessed in this document if available.

### **Data Analysis**

Analysis was done simultaneously with data collection and data preparation. All data were entered into a Microsoft® Word computer file and organized by case number. A case was composed of all observations, interviews, and medical record information obtained from and about an index patient. Each case was linked to the data generation method (e.g., interview, observation), and the place and time it occurred (e.g. pre-surgical, post-surgical, EP lab, device clinic). All recordings were transcribed and the field notes reviewed and



corrected. The transcripts were read and proofed against audio files for accuracy. Analysis followed the within- and cross-case methods Miles and Huberman (1994) described.

Each case was read in its entirety several times to get a sense of the whole (Sandelowski, 1995a). This stimulated ideas, thoughts, and impressions before moving forward in the analysis process. A contact summary form (Table 3.6) was completed that abstracted main ideas and themes, included salient points relevant to the research questions, and tracked unanswered questions and areas for further inquiry for upcoming data collection.

Codes were then assigned to words or segments of data that were descriptive or inferential in nature. Coding helped to identify key variables and themes that were later examined across cases. While coding was in progress, memos were written in which I developed ideas and thoughts about the data and began to compare elements of the data. I asked questions such as: what are they saying, what are they not saying, and in what context? Ultimately, memos helped me to explore ideas and relationships, and to identify gaps in the data.

I created data matrices to organize data, which allowed for comparisons to be made within and across cases. These matrices displayed patient characteristics, reimplantation and ICD events, psychological and social responses, and gender differences. For example, one matrix display focused on physical and psychosocial aspects of living with an ICD. Another example was a time-ordered display matrix, which contained specific elements from participants' day in surgery as clustered across cases. Event-specific matrices were also developed consisting of factors related to defibrillation threshold testing and ICD clinic follow-up visits. Analytic notes were kept throughout the project to document impressions and provide an account of analytic moves.

Aiding my analysis were concepts drawn from theories of gender and health defining masculine and feminine health behaviors within a social context, theories of adaptation to chronic illness including the body, identity, and the self, and life course theory.

**Gender.** Gender is socially constructed as an understanding of “power and social inequality” and is “something that one does recurrently in interaction with others” (Courtenay, 2000). Courtney argued that health beliefs and behaviors can be expressions and representations of gender. These cultural beliefs are formed through interactions and experiences as they are encountered within social structures, such as family, work, and healthcare environments.

Men’s health-related beliefs are influenced by societal pressures to be strong, robust, self-reliant, in control, and independent (Connell, 2005). As he suggested, hegemonic masculinity is a hierarchical structure that places a person within a dominant position in relation to others. Moreover, masculinities are developed through actions to create “configurations of gender practices” when situations change or shift (Connell, 2005, p. 77). A change in health status such as a life-threatening illness or event can restructure social relationships that threaten hegemonic masculinity. Men’s social dynamics can change when they are recognized as patients, not only in the hospital setting but also during recovery through chronicity. Men must “reformulate the definition of masculinity” because of new or lasting disabilities (Connell, 2005, p. 55).

When men are confronted with an illness such as cardiac disease, they may face identity dilemmas and uncertainty by wanting to retain their former identities (Charmaz, 1995). For example, identity dilemmas such as “autonomy versus loss of control” and “public persona versus private self” can be opposing attitudes experienced by men who live

with chronic illness (Charmaz, 1995, p. 267). Men may have difficulty accepting that they are no longer “risk-takers and winners” (Charmaz, 1995, p. 274). Power structures may change, thereby diminishing masculine status or authority. For example, a man may return home to be cared for by his wife. She may insist he avoid strenuous activities, remain calm, and abstain from sexual activities. Although the initial outpouring of attention may be appealing, men may try to re-establish hegemonic masculine behaviors as a way to maintain power and control (Robertson, 2007). Over time, however, men may view their illness or life-threatening event as a “turning point” bringing about reflection and reappraisal of their lives (Charmaz, 1995, p. 273).

Health-seeking behavior and caring for one’s health is believed to be socially constructed forms of femininity (Courtenay, 2000). Gender norms for women may be demonstrated by exhibiting behaviors as selfless caregivers who are expected not only to care for others, but also to sacrifice their own care for the needs of others (Sulik, 2007). When women are faced with a life-threatening chronic illness, Sulik (2007) suggested women engaged in a delicate balancing act between caring for themselves and normative gender expectations of caring for others. For women undergoing ICD reimplantation, caring for self may require uncharacteristic behaviors in which selflessness is no longer possible and they must balance caregiving behaviors within the family structure.

**Age.** Participants’ ages were across the adult lifespan. This presented a challenge when analyzing the data. For example, a participant may have had their initial implantation at 25 but were 40 at the time of the study. In addition, the reason for ICD implantation (i.e., cardiac arrest or cardiomyopathy) varied within the age groups changing their lives and therefore their life’s trajectory. In an effort to examine the influence of age and social

dynamics on ICD reimplantation, analysis was done within each case and within each age-group (22-39, 40-64, and  $\geq 65$ ) using principles from the life course perspective (Elder, 1994). The life course paradigm entails the concepts of historical influences and social transitions to explain adult development and social outcomes of individuals (Elder & Johnson, 2003). There are five principles in the life course paradigm that guide adult development and aging.

**1. Principle of life-span development.** Life-span development is a lifelong process. that occurs throughout a human's life. A person's mental and physical development does not end at a certain age but continues until death.

**2. Principle of agency.** Individuals are able to make choices throughout their lives within the opportunities and constraints in which they live. They are able to view their options and plan activities and actions that may influence the trajectory of their lives. For individuals with ICDs, these could be choices related to employment or ICD follow-up visits. For the very elderly patient, decisions to continue ICD reimplantation as they age may be needed.

**3. Principle of time and place.** Individuals are shaped and influenced by the historical times in which they live, as well as their location. Individuals are located within generational cohorts that experience the world in a particular context due to their place and time in history. For example, a 25-year old ICD patient who grew up with technology may feel differently about having an ICD, as opposed to an 85-year old unfamiliar with technology who may view it with wonder or suspicion. An individual's place in history includes their geographic location, cultural influences, and the meaning and values within that context. For example, in the United States today, this may include the influence of

healthcare systems on ICD implantation or the value placed on life. An individual's place may also include racial or socio-economic position within a community.

**4. Principle of timing.** The time in a person's life in which transitions, events, or turning points occur are influential in the life course. For example, age-related expectations that are considered social norms such as marriage or childbearing may have a different meaning if they occur later in life rather than when an individual is in their twenties. Similarly, if a health-related life-threatening event occurs at a young age the personal impact and meaning may vary from an individual experiencing the same event later in life.

**5. Principle of linked lives.** Individual's lives are interwoven with others in social relationships throughout the life span. When transitional events occur in a person's life, they touch others' lives that may in turn have an effect through generations. For example, if an elderly man must have an ICD reimplanted every 5 years, his children may become active participants in his decision-making and care. They in turn may become more attuned to signs and symptoms of heart disease and begin to care for their own heart health in a more positive way. Family, friends, and co-workers are primary groups in which social bonds are formed and have influence over the trajectory of an individual's life course.

## **Human Subjects**

The University of North Carolina at Chapel Hill Public Health-Nursing Institutional Review Board (see Appendix A) granted approval to the project. Prospective participants were informed of the study's purpose, what their expected involvement was to be, the risks and benefits of participation, and the right to refuse or withdraw from the study at anytime. Upon agreement to participate, individuals signed a written consent form and HIPPA authorization. A copy of these forms was then given to the participant. Because the patient

was the focus of the observation and others in the scene were at minimal risk of harm, only an oral consent was obtained from hospital staff, visitors, physicians, and nurses. A fact sheet was given to each individual that explained the purpose, participation requirements, risks, and benefits of the study. Questions were answered prior to obtaining oral consent.

### **Validity**

The study was designed to optimize the descriptive, interpretive, and theoretical validity of the findings (Maxwell, 2002). According to Maxwell (2002), descriptive validity is concerned with the factual accuracy of the data. In this study, methods to optimize descriptive validity included: (a) using audio taping during the interviews; (b) comparing transcripts with tapes for accuracy; (c) using participants' precise words in field notes; and, upon leaving the scene, (d) transcribing audio notes and creating a detailed record of events in the field notes.

Interpretive validity is directed toward accurately obtaining the actor's point of view. To optimize interpretive validity, I asked participants to elaborate on or clarify things they had said in the interviews and on observed activities. Because I have been an electrophysiology nurse for many years, I am knowledgeable about activities in device clinics and EP labs. As a researcher, however, I tried to approach the scene with an outsider's view (Patton, 2002). Spradley (1979) believed that ethnography starts with a conscious attitude of "almost complete ignorance" (p. 4). By using an outsider's approach, I sought to distance myself from events enough to gain new perspectives. In order to optimize this, I chose a hospital setting with which I was not familiar. To guard against making invalid assumptions, I asked questions of the participants, nurses, physicians, and others in the setting to clarify activities and explain behaviors after the events or procedures were

completed. I also maintained a reflexive journal (Rogers & Cowles, 1993) to track the analytic moves I had made throughout the course of the study.

Descriptive and interpretive validity form the basis for theoretical validity. Theoretical validity addresses the credibility of researchers' interpretations. Two aspects of theoretical validity are "the validity of concepts themselves as they are applied to the phenomena and the validity of postulated relationships among the concepts" (Maxwell, 2002, p. 51). To optimize theoretical validity in this study, participants were selected who could best answer the research questions. Theoretical concepts were verified across the data and assessed for fit. Ethnographic descriptions were compared with the original data sources. I also worked in conjunction with my academic advisor to provide expert oversight during each phase of the data collection and analysis process.

## **Chapter IV.**

### **Findings: Gender, Age, and the Experience of ICD Technology**

Similarities and differences between men and women with ICDs were contingent upon their social situations, their illness perceptions, and their perceptions of self. Social situations that influenced adjustment were job satisfaction, and relationships with partners, other family members, and children. These varied depending on age at initial implantation and where individuals were in the life course. For example, one woman (C.10) was implanted in her mid-30s and was now approaching 50. When she was initially implanted she was responsible for her young daughter's care despite her illness. After 11 years, however, her daughter was attending college and now provided support to her mother whenever she had surgery.

Because illness perceptions varied between individuals, their attitudes and responses differed as well. Heart rhythm abnormalities without underlying heart disease were often symptomless, which in many instances led recipients to question the need for an ICD. For those with underlying heart disease, whether they experienced symptoms influenced their adjustment. ICD recipient's initial experiences of having been diagnosed with a cardiac problem and having had a medical device implanted were significant events in their lives that influenced how they viewed themselves and interacted with others in their world.

Men's and women's perceptions of self influenced their long-term adjustment to living with an ICD. Individuals often viewed themselves differently from others. With time,



adjustment to having an ICD was integrated into their self-perception and was not a dominant defining factor in their identity.

### **Men**

Men reported varying degrees of bravado as they adjusted to living with an ICD. Maintaining their masculine persona or image was important, even though their disability was hidden or invisible to others. Men reported being unhappy when they were given unwanted attention for an extended period of time. They resented being told to restrict their activities for fear of a reoccurring event that would lead to a shock. They would challenge themselves to demonstrate to others that they were not disabled or encumbered by their condition. For example, one young man (C.9) engaged in many risky behaviors to prove he was no different with a defibrillator. He explained: “I guess I may have to prove something. I definitely have the attitude I’m not going to let it slow me down. I always had the attitude to begin with, but I think even more so now than I did back then.” He took pride in doing the opposite of what his healthcare providers recommended. He boasted of his defiance and physical prowess, such as that he scuba dived below the suggested limits, water-skied, and lifted heavy objects immediately following surgery. By pushing the limits he was proving to himself he did not have a heart condition and was essentially daring the ICD to fire. When it did not fire, it confirmed normalcy, negated his cardiac diagnosis, and reaffirmed that he was no different from other men in his age group. He admitted privately to being embarrassed and insecure about having a heart problem. He could not understand the cause for his cardiac arrest and worried about how an ICD was going to limit him. He married 10 days after his initial implantation but attributed many problems in the marriage to his wife’s over-protective behavior and his insecurities with having an ICD. His marriage ended in divorce

but with time and maturity he came to understand her concerns and reflected upon his own reckless behavior.

Men continued to reflect over time on their physical abilities, their self-image, and how they were perceived by others. One 41-year-old man (C.16) who had an ICD for 11 years continued to ponder whether he could push his physical activities to ascertain at what point the ICD would fire. He explained:

One part of me says “you need to see what your limit is, so why don’t you just run as fast as you can and see what happens,” and the other part says “well you’re going to be on the ground and that thing is going to be shocking the daylights out of you!” His initial ICD was implanted at the age of 30 and negatively affected many aspects of his life. His employer laid him off, not wanting him to work around heavy machinery. His marriage dissolved and his relationship with his children became strained. He stated he felt ashamed that he was “not manly enough and weak and fragile, and I mean, my health, it ruined my relationship [with my wife].” He worried about having another relationship with a woman because “most women want a strong man and when I mention I got a defibrillator, they start treating me like I’m fragile and I can’t depend on you and it’s just a lot of complications.” After many years of unemployment, he returned to school to be able to enter a new career field and has been striving to improve his relationship with his son. He no longer believed he was weak and fragile, but when he engaged in physical activities, he believed friends and family members at times still regarded him in that manner.

In another example, one 67-year-old man (C.4) remained active, taking care of livestock and working on his farm. He recalled several episodes in which he received a shock from his defibrillator while doing chores. In one instance he backed into his electric fence

when he was putting out a fire, thus initiating a shock. He continued with his activity as if nothing occurred. In another incident he was cleaning a deer and his defibrillator fired. He sat down, rested, and continued his activity; it was only after he experienced a second shock that he decided to seek medical attention and, even then, he denied being concerned about his heart rhythm, attributing the phenomenon to his activity.

Not all men were concerned with physical daring and masculine behavior. One 26-year-old man (C.12) who had a genetic heart condition that caused cardiac arrhythmias did not try to push his physical limits as a means to prove anything to himself or others. When he was initially implanted, he did not “take it seriously,” but when the ICD delivered a shock a few weeks after it was implanted his outlook changed. For many months he became anxious, had sleeping difficulties, and bouts of severe depression. With time and help from his family and friends, however, he was able to adjust to living with an ICD. Now, 9 years after his initial implant he had graduated from college and had a full-time job that occasionally included some heavy lifting. He did not shy away from physical exertion and expected no special treatment from his family or co-workers. He did not hesitate to tell others about his problem. He believed it was important for his friends, boss, and co-workers to be aware that he might receive a shock in order to remove the element of surprise. He found that he was able to cope much better if he was able to talk about his ICD. As he stated:

I found that the more you vocalize about it, what’s going on, the less stressful and anxiety-producing it becomes, which is why having so many people I can freely talk about it with is probably what has helped me the most.

He realized that he was dependent on ICD technology to prolong his life and was hopeful that the technology would not fail. As he noted:

Theoretically, I should never need new leads. I should be able to keep the same leads for my entire life, because they're universal for the boxes. But occasionally, like all technology they eventually, like all technology, they can fail. So the possibility of having to change out leads is always there. We just hope they stay working.

Some men attempted to resume a sense of normalcy by resuming their lifestyle and prior activities. They attempted to put their diagnosis and possibility of an ICD shock into perspective. As recounted by one 62 year old man (C.15) diagnosed with cardiomyopathy: "The way I looked at it was, you've got this heart problem, but with this, if something happens, then I should be ok." Another 78-year-old man (C. 3) minimized the ICDs significance: "I think it bothered me a little, some, but not that much. There doesn't seem to be anything to get used to."

### **Men, age, and development**

Men were affected differently depending on their age at the time of their initial ICD implantation. Three young men, age 33 (C.9), age 26 (C.12), and age 32 (C.17), had received their initial ICDs in their late teens to early 20s and had their devices for 9-10 years. Two of these three young men (C.9, C.17) had experienced a cardiac arrest requiring friends or family members to perform CPR. The causes of their cardiac arrests were not determined and they had never experienced an event since that time. A critical event such as a cardiac arrest was an untimely occurrence at this young age. Because of the sudden loss of consciousness, they talked about the cardiac arrest as family and friends had experienced it. They found it difficult to accept, particularly when they had no symptoms associated with a disease. The decision to implant an ICD was made by the physicians and family giving these men little or no input into the decision. Their ICDs became the only tangible evidence of a previous near-

death experience. As one recipient (C.17) explained: “Every time I have to fill out a form and if it asks if I have a heart condition, I always have to think about it...I have a defibrillator but I don’t have a heart condition.”

Because these young men had no recollection of the event, they were unsure of how they should act and feel. As one recipient (C.17) explained: “From what everyone was telling me, from the state of my parents and family, I was relieved to have what they thought I needed to keep me alive.” Family members and loved ones hovered and became over-protective. During the immediate post-implantation period men accepted this behavior, but with time it became unwanted.

Young men (C.9, C.17) with ICDs who became parents thought differently about having a device after their children were born. Instead of the ICD being something that might hold them back, it provided them with possibilities. They appreciated the opportunity to watch their children grow and be a part of their lives. They talked about playing and roughhousing together, but added that it was necessary to limit that play to avoid contact with the ICD. One father (C.17) remarked that he had a difficult time knowing how much to explain and what was age-appropriate when answering his daughter’s questions. He would typically rely on his wife for assistance to give his daughter a simple explanation to satisfy any curiosities. Most often the children were told it was something that was “taking care of Daddy’s heart.” The fathers anticipated having to explain more fully as their children grew but were uncertain of when or how they would accomplish this.

Receiving an ICD at a young age influenced these young men’s (C.9, C.12, C.17) transition into independent adulthood. They did not have established careers when they were diagnosed and initially implanted. They worked minimum wage jobs as they struggled to

cope with their newly diagnosed condition. Only years after their initial event did they choose to obtain additional training or to attend college. These young men received support from their parents and their friends. Two recipients (C.12, C.17) continued to live with their parents for an extended period of time following their first implantation. Relationships with their closest friends remained, but changed after their diagnosis and implantation. One young man (C.12) talked about “hanging out” with his friends. Instead of “rough-housing” they would engage in more sedentary activities such as watching movies or playing video games.

Men who received their initial ICD during their middle years (age 40-65) often had other co-morbid conditions such as coronary artery disease or cardiomyopathy along with their heart rhythm problems. This group still viewed themselves as young and vibrant, despite their heart disease. They remained active both in their professional and personal lives. Several men had partners at this time in their lives. They talked about how their partners tried to limit their activities and shelter them after their implantation. Yet, after many years with an ICD, their partners had not continued with their regulatory behaviors. They were more relaxed and less vigilant, but they maintained a presence in their partner’s healthcare decisions and experiences.

### **Women**

Women with ICDs shared many of the same sentiments as their men counterparts. They wanted to remain active and continue to work. In some instances they also had to change their professions because of restrictions placed on them by the ICD. For example, two women (S.1, C.10) were bus drivers, one for the school system and another for public transit. State driving restrictions would not allow them to continue to drive but they were able to stay within the institution or company in a different capacity. Both missed their former jobs but

were pleased and satisfied with the change. Another woman (S.4) had to change her job because she drove a long distance on a highway to get to her place of employment. She explained how difficult this was: “I had to change my job because I couldn’t drive. And it took a lot of courage to get over that. I’m proud because it took a lot to get over that.”

While women were caring for themselves they continued to care for others. Women (S.2, C.7) with young children resumed their parenting roles. Depending on the age of the children, they explained what the ICD was and how it functioned. Women voiced concern for their children and the effect their condition would have on them. One woman (S.4) with teenage children was grateful to know she would be able to see them go to the prom, go to college, and perhaps one day marry. Young women with children who did not have a spouse had to arrange childcare before going to the hospital for reimplantation surgery. They would rely on relatives or friends in some instances for several days following the surgery.

Similar to men after an ICD implant, women talked about their family trying to restrict or limit their activities. They relied on their families (husbands, sisters, or grown children) to care for them when returning from the hospital but often felt uncomfortable being cared for rather than being the person who cared for others. Yet there were women who were comfortable with the concerns of their partners, family, and friends. They enjoyed spending the extra time with them, but did not want to be pampered for an extended period. One woman (S.2) who had heart disease at a young age and her initial implantation in her twenties enjoyed this elevated status with each reimplantation. She surrounded herself with her “sister” circle each time she needed to have reimplantation surgery. This group consisted of her daughter, mother, cousins, and close girlfriends, many of whom had traveled from distant cities to stay with her before and after surgery. She explained it was a time of

gathering, sharing, and celebrating life. They reminisced about her experiences as a youth and provided support before and after her surgery.

Women exhibited caring behaviors toward others that were not just limited to family members. One African American woman (C.13) turned having a defibrillator into a crusade to help other women. She spoke at different church groups in the African American community. She believed it was important for women to be educated about their hearts so they would know the symptoms of heart disease and when to seek medical attention. As she further explained: “I feel like this is something that God gave me to tell others about, that maybe have to come in and have something like this done.” Four of the 11 women (S1, S2, C7, C13) reported drawing strength from their spirituality. They gave thanks to their God for life, for their ICD, and for providing healthcare providers with the knowledge to care for them. Although several men expressed gratitude for knowledgeable healthcare providers, they did not convey a spiritual connection to their health or wellness.

Because of a woman’s anatomy, clothing choices were important especially around the time of reimplantation. One woman (S.3) prepared the clothing she would wear to and from the hospital so she would not have to raise her arm or pull something over her head. She noted that women had the added concern of undergarments, specifically bras that were very difficult to remove following surgery. As she recalled:

The preparation entailed going out and buying front closure bras, because you can’t...and also digging out and washing and ironing every blouse that I had that buttoned down the front. Because most of the things pull over your head and when you aren’t allowed to raise you arm higher than your shoulder, it’s hard to get your clothes on.



Another woman (C.10) complained that the weight and movement of her breasts caused pain and discomfort following reimplantation surgery. In addition, she found it necessary to adjust her sleeping position in order become comfortable. Even years after the incision had healed, women (S.4, C.6, C.11) described the movement of their breasts causing some discomfort. They also found it necessary to sleep on their backs to accommodate the pressure, pinching, and discomfort from the ICD.

Women disclosed feelings of uncertainty and fear about receiving a shock. One woman (C.7) described the experience: “I was scared. It was like a big boom. Then afterward you have an electronic taste in your mouth.” Their fear diminished over time, especially if they had not experienced a shock over a period of years. As another woman (S.2) explained:

I always wondered what it would feel like until it went off and I was very scared. I was scared...So I mean you get nervous and you go about your daily activities but still in the back of your mind, you know when you feel your heart acting funny or something, it's like you're wondering what's going to happen.

### **Women, age, and development**

Young women, especially those with young children, resumed their caretaking responsibilities after ICD reimplantation. Two younger women, age 33 and 36 (S.2, C.7), were raising children independently and had no choice but to continue. On rare occasions they relied on their mothers for help when it was needed. Young women with ICDs who wanted more children questioned whether it was possible or if would be a danger. One woman (S.2) talked about wanting more children but decided against it because of the possible risks to herself and the child. She explained: “I’ll stick with what I have. Because I mean, I might not be lucky the next time, so that’s what I did. I just go from day to day.”

## **Men and Women**

### **ICD perceptions**

Men and women who had never received a shock perceived their ICD as an insurance policy; the ICD was there if it was needed. Initially, the diagnosis and implantation led to anxiety and in some cases depression. Yet, with time their anxiety diminished as they resumed their lives. As one 66-year-old man (C.8) stated:

So it's a bit of a nuisance in a way. But I haven't been nervous anticipating a shock or anything like that. The fact that it's never gone off probably contributes to that. It's been what, 8 years or something like that, I haven't...the thing's never gone off.

Men and women focused on other aspects of their lives; their heart disease and ICD moved to the background. They took pride in their accomplishments without allowing their heart condition to restrict their active lifestyles. They accepted the physical changes imposed by their ICD, but were not always happy with the physical sensation, scarring, and protrusion of the device. In some cases with each reimplantation, these characteristics could change, resulting in a period of adjustment. ICD recipients compared each implant to the other according to size and physical sensations. One 63-year-old woman (C.13) carefully chose her clothing, always cognizant and self-conscious of her scars. She always kept her shoulders wrapped in a shawl or sweater to hide the scars. Most men and women, however, gave their scars little thought, although they wished the scars would not be so noticeable. Several men expressed more concern about overall physique than over physical traits like scars.

Revealing their heart condition and ICD to others was a concern for some ICD recipients. Single men and women who did not have a significant partner had to make decisions regarding disclosure. This was usually done selectively and with the knowledge

that what was hidden from view would have to be revealed should the relationship become intimate. Men and women with intimate partners reported adjusting to sexual activity without fear of receiving a defibrillator shock. They utilized various positions so the weight of the ICD would not pinch or pull. If their heart rates quickened, they would slow down and rest before continuing.

Men and women over the age of 40 were more likely to have symptoms associated with heart disease such as fatigue, shortness of breath, palpitation, or atrial fibrillation. Five recipients (C.1, C.2 C10, C.14, C.15) had received an ICD for biventricular pacing capabilities (as opposed to having a ventricular arrhythmia) to improve the symptoms associated with cardiomyopathy and heart failure. They viewed the defibrillation function as an added bonus but were most concerned about the strength of their heart muscle. They credited the ICD with giving them more energy, keeping them out of the hospital, and improving their overall heart function. They referred to their ejection fraction (a percentage used to assess cardiac function) as it went from “bad to good” as well as their other symptoms to evaluate their health status. Participants committed their ejection fraction percentages to memory, using it as an indicator of wellness over the months and years since being diagnosed. Participants viewed ICD technology not as a cure, but as a way to control their “heart problem.” They gave little attention or thought to the possibility of an abnormal heart rhythm and the shocking capabilities of the device.

Men and women used their ICD as an informative tool. They anxiously waited when their ICD was interrogated to learn if they had any detectable cardiac dysrhythmias. When any detectable abnormality occurred, they inquired about the date and time, believing some stressful event or physical activity may have caused the problem. The information stored in

the ICD provided verification that they did indeed have a cardiac condition and confirmed the necessity of the device. One 54-year-old woman (S.5) often questioned whether the ICD was really doing anything because she had not received a shock for many years. She wanted to know, “Is that machine really helping my heart out or is it just there?” ICD interrogation provided credible evidence of device monitoring and function. If no events were recorded, it substantiated a person’s wellness perception, making it plausible for the ICD recipient to dismiss an illness identity.

### **Social support**

Long-term ICD recipients settled into the routines of life, except during the time of reimplantation. They relied on their families or friends to help and support them at that time. Reliance on friends and family members was a recurring theme with all ICD recipients. This diminished over time after the first implantation. With the first implantation, recipients may have survived a cardiac arrest or received a diagnosis of a myocardial infarction or heart failure. Because peoples’ perceptions of heart disease, much like cancer, tend to be associated with life and death, the incident reshaped the lives of both the patient and family.

In some cases, friends or family members were witnesses to their loved one’s cardiac arrest and played a vital role in the resuscitation effort. This had significant meaning for ICD recipients and continued to invoke strong emotions years later. ICD recipients who had experienced an out-of-hospital cardiac arrest expressed heartfelt empathy toward family members directly related to this experience. Two young men, age 33 and 32 (C.9, C.17), were especially emotional talking about their parents and what the experience was like for them. They became choked-up, teary, and unable to express all the emotions they were feeling. One 53-year-old woman (S.4) had teenage children who experienced her near-death

incidents. She was overwhelmed with emotion when she talked about how they must have felt watching her go through the experience.

Middle-aged and older adults with ICDs relied heavily on their adult children and spouses for help and assistance. Following their initial implantation they were faced with over-protective behavior from their families. Yet, as ICD recipients managed active lifestyles with no adverse consequences, family members became less protective. Their protective behavior did not return following reimplantation. Perceived as a “minor” one-day procedure, reimplantation did not carry the same life and death implications associated with the initial implantation.

Only one 64-year-old recipient (S.3) and her daughter perceived reimplantation differently. She had life-threatening complications following the first ICD implantation. Accordingly, she approached her upcoming procedure with fear and dread. She and her daughter were extremely anxious and insisted on having only the attending physician perform the surgery. Her anxiety negatively affected her sedation during the procedure, which might further influence her sentiments about reimplantation in the future.

Many older ICD recipients had comorbid conditions affecting interrelationships with family and friends. For example, several were diabetic or had severe cardiomyopathy and were dependent on oxygen. Sons, daughters, sisters, or possibly a friend assisted with their daily care and transport needs. They still tried to maintain some independence despite their disability. Having an ICD was a small part of the whole experience of chronic illness, given minimal significance within the scope of their disease.

## **Financial concerns**

Recipients had financial concerns as they anticipated ICD replacement surgery. They realized that the financial burden of having an ICD was ongoing for the remainder of their lives. Even those with private insurance had additional costs not covered by their insurance. One 53-year-old woman (S.4) remarked: “I’m sure it’s going to cost a bloody fortune, because you have to pay a \$600 deductible plus 20% of a huge bill.” She and her husband planned for her ICD replacements, setting money aside to cover these costs. When her reimplantation occurred sooner than expected, they had to make budgetary adjustments to accommodate the change.

Two ICD recipients (C.12, C.17) used a payment plan set up by the hospital to pay for their device implants. They expressed gratitude that the healthcare facility allowed them to do this, but also realized it would be an ongoing dilemma. As one 32-year-old man (C.17) explained: “We set up a payment plan. I’ll be paying monthly installments to the hospital for the rest of my life.” A 66-year-old man (C.8) observed:

The last one I had didn’t last that long. It was 4 years or something like that. They told me about 7. And that bothered me some. You know if I have 20 years left and I have to have a new one every 4 years, that’s a lot of replacements.... I think my dislike of having these things repeatedly replaced is about 50% expense and 50% hassle, but what are you going to do?

ICD recipients who were on Medicare or Medicaid were not concerned with the financial strains of reimplantation surgery. They had little or no overages to pay and did not express any hardship related to cost.

ICD reimplantation required recipients to be away from their jobs for several days to a week following their surgery for healing and recovery. For those who were working minimum-wage jobs, lost time was lost wages. One 26-year-old young man (C.12) with this type of employment had a required hospital stay for which he had to arrange a short medical leave to insure his position when he returned. Yet, other ICD recipients had sick-time benefits that did not present a financial challenge.

### **Decisions about replacement**

Long-term ICD recipients who had never received a shock and had no detectable cardiac arrhythmias upon ICD interrogation questioned the need to continue having their ICD replaced. For example, one 66-year-old man (C.8) who had problems with underlying heart disease had never been shocked. He explained:

The evidence is that I'm not in great need of this thing. I think when the time comes, when the battery runs down, I'll make another effort to suggest that maybe the thing is not as necessary for me as it is for other people. I wouldn't mind terribly much if they didn't want to put another one in.

He talked with his wife but she insisted he have it replaced. He further explained:

I've been totally stable and no problems. So it seems like it is a bit of overkill. But I'm not going to...but who am I to argue with my wife! I'm hoping at some point or another, they can say that we'll take it out and we don't need to put another one in.

Having young children influenced how one 32-year-old father (C.17) felt about having surgery. As he observed: "I now have two kids. Granted I was married at the time (with the first replacement) but I have much more to lose, so to speak, this time if something were to happen." He wrestled with the risk imposed by surgery and the actual need for the

device. Because he never experienced any symptoms from an aberrant heart rhythm or an ICD shock, he questioned the need to be reimplanted. He discussed it with his wife (who was in favor of replacement), but he asked his physician to reevaluate his cardiac status before making his decision. He underwent several diagnostic procedures, which revealed no detectable cardiac abnormalities. He decided to proceed with the surgery and explained his decision simply as “kind of a backup plan now that I got it. I don’t crash my car but I still wear a seat belt.”

ICD device recalls also influenced participants’ decisions to have their ICD replaced. ICD and lead recalls had occurred in the past requiring some patients to have their devices replaced sooner than expected. One 63-year-old woman (C.13) who needed a new ICD because of a recall had concerns about the safety of the device. As she recalled when talking it over with her sons: “I was getting to the place where I told my children I don’t know if I want another one of these in because these things aren’t safe.”

Participants who believed their ICD was prolonging their life by pacing to prevent a bradyarrhythmia or to synchronize their ventricles, or by stopping ventricular arrhythmias, never questioned the need for reimplantation. This was true across all age groups regardless of the reason for their initial implantation. They believed their ICD was the reason they were able to live a “normal” life by increasing their energy level and diminishing the fear of sudden death.



## **Chapter V.**

### **Discussion**

The findings concerning long-term adjustment to living with an ICD were characterized by both differences and similarities according to sex and age. Men often exhibited bravado and were likely to engage in risk-taking behaviors. Women remained engaged in caring behaviors following implantation and surrounded themselves with other women as their support network. Young women were also concerned about childbearing once they had an ICD. Both men and women were concerned about reimplantations; the risks, technology reliability, financial strain, scarring, and continued follow-up for years to come. Their initial implantation caused concern and angst that diminished over time, thereby moving the focus away from the ICD to other aspects of their lives.

Men and women shared many characteristics related to their experience with having an ICD. Both were determined to resume a normal life with few restrictions or limitations. With time they rejected family members' overprotective behaviors and strove for independence. Men were more likely to take this to an extreme, pushing their physical limits regardless of the consequences to prove their masculinity. Young women as well as men were hesitant to reveal or acknowledge their heart condition to co-workers or friends. Because their disability was not visible to others, they chose to exhibit behaviors to continue the illusion of good health. This avoidance to reveal their condition was an attempt to "counter the effects of stigma and fit in socially" with others in their age group (Joachim & Acorn, 2000, p. 43). Matthews and Harrington (2000) suggested that when a young person

reveals an invisible disability, especially heart disease, their peers also perceive them as being contextually older. Not only do others perceive those with invisible disabilities to be older but persons with the disability perceive themselves in the same manner (Kundrat & Nussbaum, 2003). In addition, several young ICD recipients created self-imposed expectations for success that, when not met, resulted in feelings of insecurity, anxiety, and concern about how others perceived them (Matthews & Harrington, 2000).

ICD recipient's relationship with their implanted technology varied somewhat according to generational differences. Younger recipients (less than 40) have experienced technology in some manner all their lives. They have seen computers diminish in size and increase in capabilities. Their expectations for ICD technology mirror these qualities. That is to say, not only do they expect the technology to get smaller, but also last longer. Yet, researchers have found that when given the choice, ICD recipients preferred device longevity over size (Wild et al., 2004). The desire for device longevity to increase the time between device reimplantations was shared among all age groups. The size and resulting disfigurement it caused was not as great a concern, but was more significant for recipients who had a slimmer physique regardless of their gender. Younger ICD recipients also expected that medical research and ingenuity might, at sometime in their lives, eliminate the need for an ICD altogether.

Younger ICD recipients had some unique challenges following implantation. Several had experienced and survived a cardiac arrest that affected both themselves and others close to them. Kellehear (1990) examined near- or anticipated-death experiences and their effect on identity and social networks. He suggested that after such events, persons reflect on the meaning of their life and what that loss would mean to others. Family and friends recount the

event from their point of view, placing the person through a period of “stigmatized and elevated status” (Kellehear, 1990, p. 937). This status may be unwelcomed by some individuals, yet they may feel empathetic toward the friends and family that comprise their social network.

ICD recipients in their middle years (40-65) were more accepting of their devices and were more likely to have comorbid conditions than younger recipients. Most had established careers and stable personal lives. They took pride in their accomplishments and the fact that they had not allowed their heart condition to restrict their active lifestyle. Their lives were often linked to partners and/or their children who were influential in their healthcare decisions regarding their ICD. Women continued to display caring attitudes and behaviors toward their families and others following ICD implantation. They continued to run the household and manage their families, thereby creating a positive self-image and a way to maintain their previous selves (Charmaz, 1987). They remained active and believed the technology provided a sense of security, even though it could be anxiety-provoking when they received a shock (Goldstein et al., 2008).

Older (>65) ICD recipients were fascinated by computer technology and marveled at its lifesaving capabilities. They were living in a time when medical technologies could assume physiologic function of vital organs and extend life expectancies. Medical advancements have changed the face of aging and legitimized interventions that are now the standard of care (Shim, Russ, & Kaufman, 2006).

The oldest (>65) age group expressed gratitude for their ICD. They believed their healthcare providers would provide expert advice regarding the need for reimplantation (Ågård, Löfmark, Edvardsson, & Ekman, 2007). By having an ICD, however, they might

also be exposed to a longer period of illness due to co-morbidities and face a long lingering death (Kaufman, Mueller, Ottenberg, & Koenig, 2011; Shim et al., 2006). These researchers explained how technology intended for one use, to decrease the incidence of sudden death, has become the standard of care for individuals of all ages, including the elderly. By removing the possibility of sudden death from a cardiac arrhythmia, patients can no longer hope to “die in their sleep,” a quiet and pain-free death that many may desire. Elderly ICD recipients in this study denied giving thought to the end of life and decisions regarding their ICD. They expressed a desire to live as long as possible in good health, accepting life day to day, not wishing to die a painful tortured death. They attributed having an ICD to providing their longer life, whether or not the ICD had delivered life-extending antiarrhythmic therapy such as a shock and antitachycardia pacing.

Whenever an elderly ICD recipient faces reimplantation due to battery depletion, the decision to continue this treatment modality is made judiciously. Researchers found that healthcare providers tend to approach and present medical procedures, such as ICD implantation as low risk. They use language such as “routine,” “no big deal,” and “you’ll be fine, you have nothing to worry about” (Shim et al., 2006, p. 484). In addition, individuals waiting for surgery characterized their procedures as “like an assembly line” but also felt reassured by the “routineness and institutionalization” of the procedures. Patients and their families may be reluctant to refuse this treatment option for fear of “authorizing their own deaths” (Kaufman et al., 2011, p. 12). Participants observed in this study before undergoing reimplantation were similarly informed of the surgical risks and defibrillator threshold testing, while concurrently being assured that nothing would go wrong. By downplaying the significance of the event, healthcare providers confirmed the routineness of the surgery and

the impact of inducing ventricular fibrillation on their hearts. Most participants in this study wished to continue to have ICDs reimplanted regardless of their age, but with the caveat “as long as I’m healthy.”

Differences were noted between recipients who had received delivered therapy (i.e., shocks or antitachycardia pacing) from their ICD and those who had not; this directly affected their illness and identity perceptions. Most ICD recipients were symptom-free until their lives were disrupted by such an event. As many with many chronic illnesses, ICD recipients experienced shifts in identity when these events occurred (Charmaz, 1987). Charmaz (1987) explained that persons experiencing illness choose a preferred identity often dictated by the degree of illness. She identified four hierarchical forms of identity: (a) a supernormal identity by which individuals attempt to over-achieve to draw accolades and praise from others; (b) a restored self by which individuals return to their former activities and self before their illness; (c) a contingent personal identity in which persons will evaluate the risks and benefits to resume their prior identity; or (d) a salvaged identity when illness causes some disability and a person strives to retain a positive attitude and feelings of worthiness. Persons experiencing chronic illness might also predict experiences before they occurred so they can plan their “identity objectives” (Charmaz, 1987, p. 291). For example, patients anticipating ICD reimplantation may inform family members of their anticipated disability following surgery. This varied widely with participants as they described the time it took for recovery and their ability to return to their previous state. Identities shifted when symptoms occurred or after a shock event was experienced. Similarly, Paterson (2001) suggested when a person’s illness shifts to the foreground it becomes the focus of their lives; it also confirms the reality of their condition to others. ICD recipients who go through the

reimplantation experience, have a shock, or experience symptoms must respond to these conditions thereby moving away from a wellness identity. These shifts from wellness or illness in the foreground of peoples' lives may be precipitated not only by the onset of symptoms, but also by their wish to "revise" their identity, in which the "the self and not the diseased body becomes the sources of identity" (Paterson, 2001, p. 23).

ICD recipients understood the permanency of having an implanted device as a measure to prevent sudden cardiac death or ameliorate health should they have underlying heart disease (Williams, Young, Nikoletti, & McRae, 2007). Participants' illness perceptions varied widely depending on symptomatology. Approximately half of the participants did not exhibit symptoms but viewed their ICD's antitachycardic activity or its diagnostic recordings as indicators of their health status. This is similar to the results from other studies directed toward examining issues related to invisible disease, such as T-cell counts in HIV or bone density tests for osteoporosis (Sowell, Phillips, Seals, Misener, & Rush, 2001; Weston, Norris, & Clark, 2011). These researchers concluded that people valued tangible evidence, such as lab values and diagnostic tests, as a way to assess their health status.

Finally, the results found in this study for ICDs may be comparable to other types of implanted devices. Similarities to consider are the corporal sensations experienced by recipients of technological devices, the possibility of repeated surgeries, and the influence of illness perceptions as individuals adjust to their devices. For example, persons with implanted central venous access ports for hematology or oncology treatment have reported the sensation of a foreign object in their body, occasional discomfort, and difficulty keeping their disease private due to the visibility of their port (Goossens, Vrebos, Stas, Wever, & Frederickx, 2005). The decision to implant these devices, similar to ICDs, was usually on the

recommendation of the physician as a beneficial or preferred option to treat their condition. Yet, comparing the experience of individuals with implanted devices may vary widely because of factors related to permanency, necessity, and purpose. In the previously mentioned example of an implanted central venous port, the device is often temporary and may be removed after the patient's treatment is completed. Reimplantation may occur in the future should treatment modalities be resumed. In contrast, ICDs are considered to be an irrevocable treatment modality that will remain over the course of a person's life. In rare cases, ICDs may be explanted but these decisions are made after evaluating each case thoroughly to assess patient's cardiac disease and arrhythmia history (Geist, Newman, Greene, Paquette, & Dorian, 2000). Other implanted technologies such as breast implants or cochlear implants may offset physical and sensory deficiencies, but do not carry the same life-sustaining indications as ICDs or pacemakers. Moreover, a decision to implant these types of devices ultimately rests with the recipient or parent and is not made with the same urgency as ICD implantation (Cordeiro, 2008; Li, Bain, & Steinberg, 2004).

### **Clinical Implications**

Implanted technologies are commonplace in the landscape of health care today. Patients with these devices are seen throughout the healthcare system. Healthcare providers in general and nurses caring for these patients need to be aware that gender and location in the lifecourse may influence adjustment to living with an ICD. Understanding where an individual is within place and time, as well as where they are at that precise time in their lives may account for many aspects of their acceptance, adjustment, and recovery.

Men and women exhibited similar characteristics related to the physical adjustment of having an ICD. Both men and women showed self-consciousness about their appearance

although this was not always the case. Age did not appear to be a contributing factor in responding to the physical attributes of an ICD. Additional reimplantation surgery might result in multiple scars adding to their perceived disfigurement. Educating patients on the types of clothing to conceal their devices may be beneficial. They should also be encouraged to speak to their healthcare provider prior to reimplantation surgery to discuss options related to their incision, ICD placement, or possible scar revisions (Cassagneau et al., 2001; Sowell et al., 2006).

Patients returning home with a new-model ICD can be expected to be concerned about the difference in how the device feels and how it will behave. Will it be the same as the device just explanted? Will this ICD give me a shock? They will engage in a waiting game, hoping it will be just as it was before. Once they move past a self-imposed grace period, their vigilance will diminish and a sense of normalcy will return.

Elderly ICD recipients with end-stage heart disease should be encouraged to begin a conversation with their healthcare provider to stay informed about the available options regarding their ICD and end-of-life decisions (Goldstein et al., 2008; Stewart et al., 2010). Many are unaware that the shock function can be disabled, thereby decreasing the possibility of multiple painful shocks as they approach death.

Although an unusual occurrence, those who experience maladjustment due to reimplantation issues may need to seek further assistance from healthcare professionals. Previous intervention study findings suggest methods to improve the quality of life and psychosocial functioning of ICD patients following their initial implantation, which may be helpful for the reimplantation population as well (Dougherty et al., 2005; Dunbar et al., 2009; Edelman, Lemon, & Kidman, 2003; Sears, Conti, et al., 1999). Healthcare providers may be



able to identify signs of distress such as reports of insomnia, fear, or anxiety, when ICD recipients are being seen during device clinic visits or for other routine medical care. Yet, newer more advanced ICDs are being interrogated via telephone thereby decreasing the number of visits to the device clinic. Providers should not only provide information about what to do in event of a shock, but also when to contact someone for assistance regarding related physical, psychological, or social issues (Sears & Conti, 2002).

### **Research Implications**

Future research on long-term adjustment and acceptance is warranted especially among the youngest recipients. Complications from implant surgery and new technologies may change the outcomes for this population in years to come. Longitudinal studies or in-depth case studies over an extended number of years with varying data collection points may reveal new insights into the effects of recurrent implantation. For example, in this study I examined the experience of ICD recipients with 1-3 reimplantation procedures but younger recipients may endure a lifetime of recurrent surgery with a much greater number of reimplantations. Studying the effects associated with implanted technology over an adult's lifetime would provide insight into those experiences. What are the effects of having multiple devices perhaps placed in different locations on the chest wall with multiple leads? How has having multiple shocks or treatment for arrhythmias affected lives, relationships, and well-being over the life course?

Studies examining specific race and economic considerations may also be beneficial. Researchers have identified some disparities related to ICDs as an intervention for cardiac arrhythmias among certain populations (Gauri, Davis, Hong, Burke, & Knight, 2006; Groeneveld, Heidenreich, & Garber, 2005; Stanley, DeLia, & Cantor, 2007), but these have

not been fully explored. For example, several African-American women in this study used spiritually and their church family as a support network. They spoke of their strength within their own family and their desire to help other African American women who often are under considerable stress as—in the words of one woman—both the “man and woman in the house.”

Financial issues have been touched upon in this study, but future research is needed to study the economic effects and costs of repeated implantation. American healthcare reform may affect future generations as access to devices and implantation criteria are affected. Ethical and social justice issues warrant study in this population. Researchers have begun to examine ethical considerations with the elderly, including those related to death and dying and end-of-life care but more study is needed (Braun, Hagen, Hatfield, & Wyse, 1999; Kaufman et al., 2011; Sulmasy, 2007).

### **Limitations**

This ethnographic study was limited because of the time constraints of a dissertation study and lack of a long-term relationship with key informants. The observations in the EP lab during implantation were all women. This was due to randomly selecting the first five participants who were willing to be observed during surgery. In addition to the five women observed during surgery, one man was observed during the pre-implantation phase but was not observed throughout the entire procedure due to surgery postponement. This may have had a limiting effect on the study. Men and women might have been approached differently in the lab environment that would affect or influence how ICD recipients viewed the process.

Socioeconomic data were not obtained during data collection. This information would have added to the depth of age-related findings particularly for the middle and elder cohorts.

Data from the medical records was limited to the charts maintained in the device clinic. Medical histories were not extensive, making the initial reason for implantation difficult to evaluate. ICD-recorded printouts were available when an arrhythmia had occurred, but if the participant was treated in the hospital between clinic visits, that information was not available except through the electronic hospital medical record. Future studies might need to include access to all medical records from the hospital facility.

## **Conclusions**

As the ICD recipients age, necessity will dictate ICD replacement surgery with an ever-increasing risk of device and lead-related complications. Engineers and physicians are partnering to improve technology to reduce this risk. A recent development in ICD technology may eliminate transvenous leads and use a completely subcutaneous system for arrhythmia detection and defibrillation. Researchers testing this device in a multicenter study have reported successful rhythm detection and defibrillation during defibrillator threshold testing and success in 12 spontaneous episodes in patients who were implanted in a European trial (Bardy et al., 2010).

Recipients of ICD technology are committed to many years of recurrent surgery and follow-up. Healthcare providers need to be aware of the influences of gender and development on patients as they are engaged in their care. This study of long-term adjustment for patients with implantable cardioverter defibrillators will hopefully increase the awareness of this life-saving technology and the influences it may have on a patient's life, thereby providing knowledge for nurses to be better equipped to educate and advise patients about future expectations. In addition, specialty nurses directly involved in ICD

reimplantation and follow-up may gain new insight in order to develop evidence-based care practices to be utilized during the perioperative and implantation period.

Table 3.1.

*Sample Characteristics*

Sample Code	Age	Sex	Primary or Secondary Prevention <sup>a</sup>	Race	Number of Replacements (after initial ICD)	Years / ICD	Time since last implant→ interview	S/P cardiac arrest	Current Cardiac symptoms	ICD Shocks or ATP	ICD or CRT-D device <sup>b</sup>
S.1	72	F	S	AA	2	12	1.5 weeks	yes	none	yes	ICD
S.2	33	F	S	AA	2	11	3 months	no	None	yes	ICD
S.3	64	F	S	CA	1	7	2 weeks	no	VT, CHF	yes	ICD
S.4	53	F	S	CA	1	6	2 weeks	yes	occ. palpitations	no	ICD
S.5	54	F	S	AA	1	5	4 months	yes	CHF	yes	ICD
C.1	85	M	P	CA	1	6	2 years	no	Occ. AF with chest pressure	yes	CRT-D
C.2	76	M	S	Basque	1	7	6 months	no	Occ. SOB	yes	CRT-D
C.3	78	M	S	CA	2	9	5 years	no	AF, SOB	yes	ICD
C.4	67	M	S	CA	1	8	1 year	yes	none	yes	ICD
C.5	75	F	S	AA	1	8	1 year	no	CHF	yes	ICD
C.6	80	F	S	CA	2	8	5 year	yes (hospital)	O <sub>2</sub> Therapy none	(hospital) no	ICD
C.7	36	F	S	AA	2 1 lead extraction (3 surgeries total)	10	1 month (ICD) 2 weeks from lead extraction	no	None	yes	ICD
C.8	66	M	S	CA	2	8	3 years	yes (hospital)	none	no	ICD
C.9	33	M	S	CA	1	10	4 year	yes	None	no	ICD
C.10	49	F	S	AA	2 1 epicardial lead addition (3 surgeries total)	11	3 months	yes (hospital)	CHF symptoms	yes	CRT-D
C.11	77	F	S	CA	1	9	1 year 5 months	no	O <sub>2</sub> Therapy, CM	no	ICD
C.12	26	M	S	CA	1	9	6 months	yes	Occ. Palpitations, tachycardia	yes	ICD
C.13	63	F	S	AA	2 1 lead revision (3 surgeries total)	13	2 months	no	None	yes	ICD
C.14	54	M	P	AA	Pacemaker (initial)→ CRT→CRT-D (2 replacement surgeries total)	4	3 weeks	no	Occ. Fatigue,	yes	ICD
C.15	62	M	P	CA	2	6	1 year 5 month	no	None	no	CRT-D
C.16	41	M	S	AA	2	11	4 months	no	Fatigue,	yes	ICD
C.17	32	M	S	CA	2	10	2 weeks	yes	None	no	ICD
C.18	53	M	S	CA	1	10	5 year 1 month	no	Fatigue, SOB	no	ICD

*Note.* Sample code: S=surgery observation and interview, C= clinic observation and interview; M=male; F=female; AA= African-American; CA- Caucasian; CRT-cardiac resynchronization therapy pacemaker; CRT-D=cardiac resynchronization therapy defibrillator; S/P cardiac arrest= status post cardiac arrest prior to getting an ICD; ATP=antitachycardia pacing; VT= ventricular tachycardia; CHF= congestive heart failure; CM= cardiomyopathy; SOB=short of breath; occ.=occasional; AF=atrial fibrillation; O<sub>2</sub>=oxygen.

<sup>a</sup> Primary prevention= No past episode of VT, ICD implanted because of increased risk; Secondary prevention= Episode of VT/VF in past, prevention of a secondary VT event; <sup>b</sup> ICD=implantable cardioverter defibrillator (one lead in the right ventricle to shock or pace); CRT-D=cardiac resynchronization therapy defibrillator (one lead in right ventricle and one lead in left ventricle, paces ventricles synchronously; right ventricular lead has shocking capabilities).

Table 3.2

*Reimplantation Observation Guide* (Adapted from Spradley, 1980)

1. What are the physical spaces and characteristics in the Electrophysiology holding bay and EP Lab?
2. Who are the people in the scene?
3. What activities are going on with those in the scene?
  - a. Preparation for surgery: health assessment, starting IV, consent procedure, teaching, monitoring, waiting
  - b. EP lab: transport to room, turning off ICD, surgical scrub and draping, sedation, surgical procedure, ICD testing, patient waking and removal from room
  - c. Recovery: Check surgical site, monitoring for complications, discharge teaching
4. What objects are in the scene? (medical equipment, x-ray machine, computers)
5. What are people doing in the scene?
  - a. What is the patient doing? (interaction with nurses, physicians, staff and visitors)
  - b. What are the nurses doing? ( tasks being performed, interactions with others)
  - c. What is the ICD Company Representative doing? (interaction with patient and others, checking ICD, programming new ICD, conducting ICD test)
  - d. What does the physician do? (interactions with patient and others, surgical procedure)

- e. Do other healthcare professionals enter the scene? What are they doing? (e.g., x-ray or lab technicians, secretaries, aids)
  - f. Are there any visitors present? What are they doing ? (if any, pre-and post-op, interaction with patient and others)
6. How do they interact with each other and physical objects in the room?
  7. What are the participant's responses to the activities in the scene? (verbal and non-verbal)
  8. What is the time sequencing throughout the procedure?
  9. What is being accomplished at each stage of the procedure?
  10. What and how are people communicating both verbally and non-verbally?
  11. What expressions and emotions, if any, are being displayed by the patient and others?

Table 3.3.

*Device Check Observation Guide* (Adapted from Spradley, 1980)

1. What are the physical characteristics of the device clinic?
2. Who are the people in the scene?
3. What activities are going on in the scene?
  - a. Positioning in chair and monitoring equipment applied
  - b. ICD interrogation, data retrieval
  - c. Lead testing
  - d. Programming changes (if any)
  - e. Preparation for future appointments
4. What objects are in the scene? (ICD programmer, medical equipment)
5. What are people doing in the scene?
  - a. Who directs/manages the patient? What is the patient's response?
  - b. What does the nurse do and in what order?
  - c. Does anyone else enter the scene? What do they do?
  - d. Are there family, visitors present? What are they doing in the scene?
6. How do they interact with each other and physical objects in the room?
7. What are the participant's responses to the activities in the scene? (verbal and non-verbal)
8. What is the time sequencing throughout the procedure?
9. What is being accomplished at each stage of the procedure?
10. What and how are people communicating both verbally and non-verbally?
11. What emotions, if any, are the actors displaying?



Table 3.4.

*Interview Guide*

1. Can you tell me the story of how you came to have an ICD?
  - a. Did you have an abnormal heart rhythm or was it put in just in case?
  - b. Can you tell me what it was like when you went home?
  - c. What were some of the physical sensations, if any, you experience related to your ICD?
  - d. Can you remember how you were feeling (emotionally) at that time?
2. Can you tell me about living with an ICD?
  - a. Many people experience a range of different emotions when they have a defibrillator. Can you tell me about the feelings you experienced?
  - b. Do you feel differently about yourself? Has that stayed the same or changed over a number of years? If it changes, what do you attribute those changes to?
  - c. If the reply is “you just deal with it”, Can you tell me how you do that?
  - d. How often do you think about your ICD?
3. Do you think having an ICD has affected your life, if so how?
  - a. How has it affected your family relationships?
  - b. How has it affected your professional relationships?
  - c. How has it affected your social relationships?
4. Have you ever experienced a shock? Can you tell me about the experience(s)?
  - a. Where did it happen? Were others present?
  - b. What was the physical sensation?
  - c. How did you feel emotionally before, during, or after the shock?

- d. Did you feel differently about your ICD? How did it affect your life? Does it change with each event?
5. Can you tell me about having your ICD checked/interrogated?
  - a. Do you have any physical sensations during the procedure?
  - b. How do you experience any emotions before, during, or after the check?
  - c. Have you ever been told your ICD stopped a fast heartbeat (arrhythmia) and were unaware of it happening?
  - d. Do you worry about the battery in your ICD?
6. Tell me about your second ICD (and each successive ICD if applicable).
  - a. What were your thoughts and feelings when you knew it was almost time to have the surgery?
  - b. Did you have your ICD replacements (if >1) at the same hospital(s)?
  - c. Tell me your thoughts and impressions of your day(s) of surgery.
  - d. Was the experience different from your other implant(s)? If so, how?
  - e. Did you feel any discomfort during the procedure? After? For how long?
  - f. Do you ever think about not having your defibrillator replaced?
  - g. What if anything, changes (has changed) with your new implant(s)? (e.g., physical, emotional, or social variations)
7. Can you tell me about the test (VF induction/defibrillation) they do with the ICD during surgery?
  - a. Do you remember the doctors telling you about that?
  - b. How do you feel about that?
  - c. Did you talk to anyone about your thoughts and concerns?

Table 3.5.

*Medical Record Data Extraction Guide*

Demographics:

Age \_\_\_\_\_

Age at implant \_\_\_\_\_

Sex \_\_\_\_\_

Employment status \_\_\_\_\_

Marital status \_\_\_\_\_

Others in Household

None \_\_\_\_\_

Partner \_\_\_\_\_

Children \_\_\_\_\_

Others \_\_\_\_\_

Medical Information:

Diagnosis \_\_\_\_\_

Reason for original implantation \_\_\_\_\_

Type of ICD \_\_\_\_\_

Present LVEF/ or NYHA classification \_\_\_\_\_

Arrhythmia history \_\_\_\_\_

Number of years with a defibrillator \_\_\_\_\_

Number of previous ICDs (include initial implant) \_\_\_\_\_

Dates \_\_\_\_\_

Shocks \_\_\_\_\_ ATP \_\_\_\_\_ (Since original implantation)

Considered appropriate \_\_\_\_\_ inappropriate \_\_\_\_\_

Physical location of implant(s) \_\_\_\_\_

Complications \_\_\_\_\_

Recalls \_\_\_\_\_

Frequency of ICD checks/interrogations \_\_\_\_\_

ICD Programming Parameters \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Table 3.6.

*Contact Summary Form* (Adapted from Miles and Huberman, (1994, p.53)

Participant Case Number \_\_\_\_\_ Date \_\_\_\_\_

Number of Implants \_\_\_\_\_

Reason for Reimplantation \_\_\_\_\_

Implant indication (primary vs. secondary) \_\_\_\_\_

Gender \_\_\_\_\_

Race/Ethnicity \_\_\_\_\_

Age (present) \_\_\_\_\_ Age (initial implantation) \_\_\_\_\_

Years with an ICD \_\_\_\_\_

Location/Setting \_\_\_\_\_ Time \_\_\_\_\_

What main issues or themes that came to light with this contact?

Summarize the information you got (or failed to get) about the following:

History of implantation

Shock or ATP therapy

Psychological changes (if any) initially and over time

Social changes (if any) initially and over time

Physical characteristics-concerns

Interaction with the technology (i.e. sentiment toward the technology)

Sentiments toward surgery

Positive-Negative

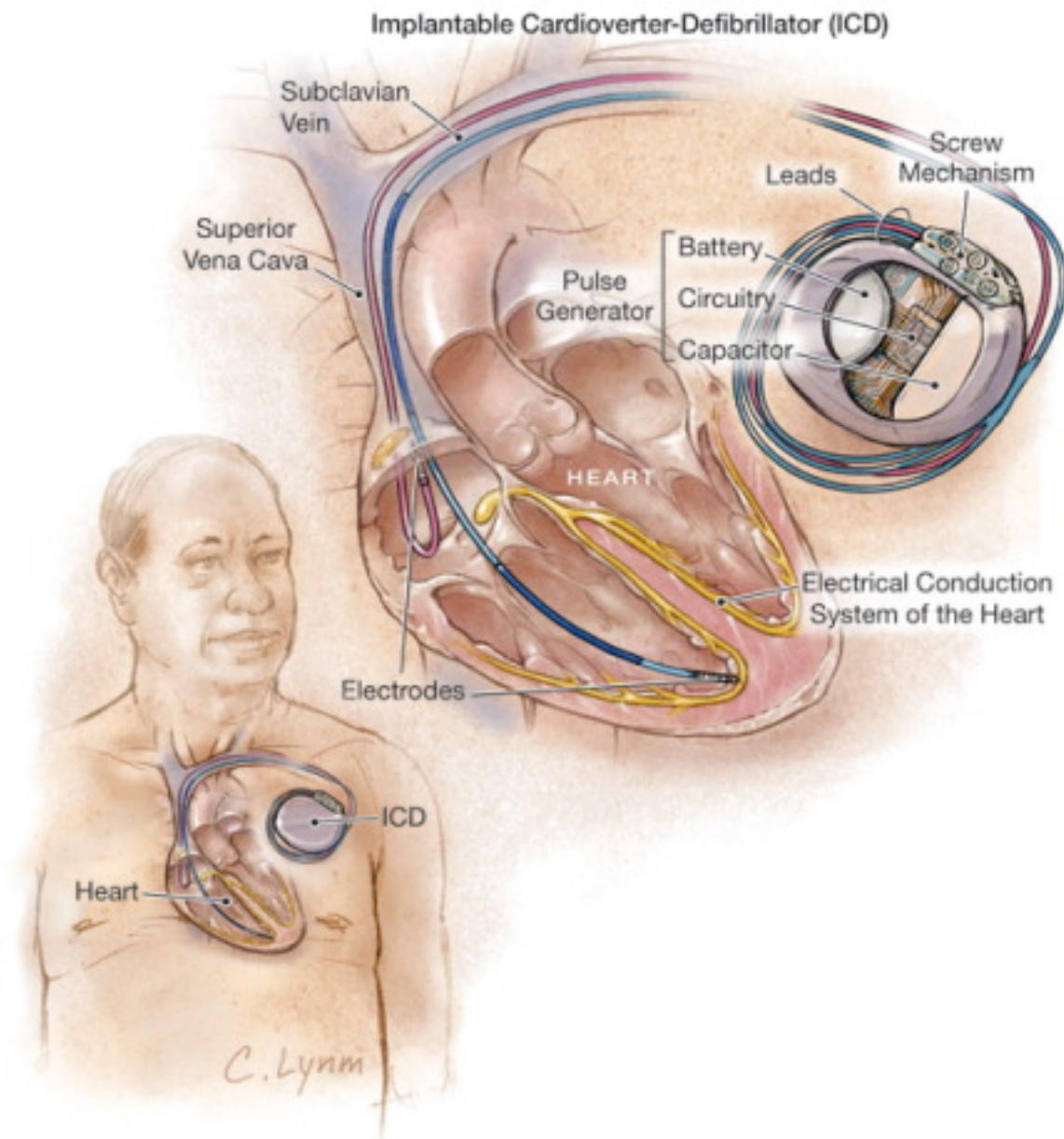
Life interruption

Pain

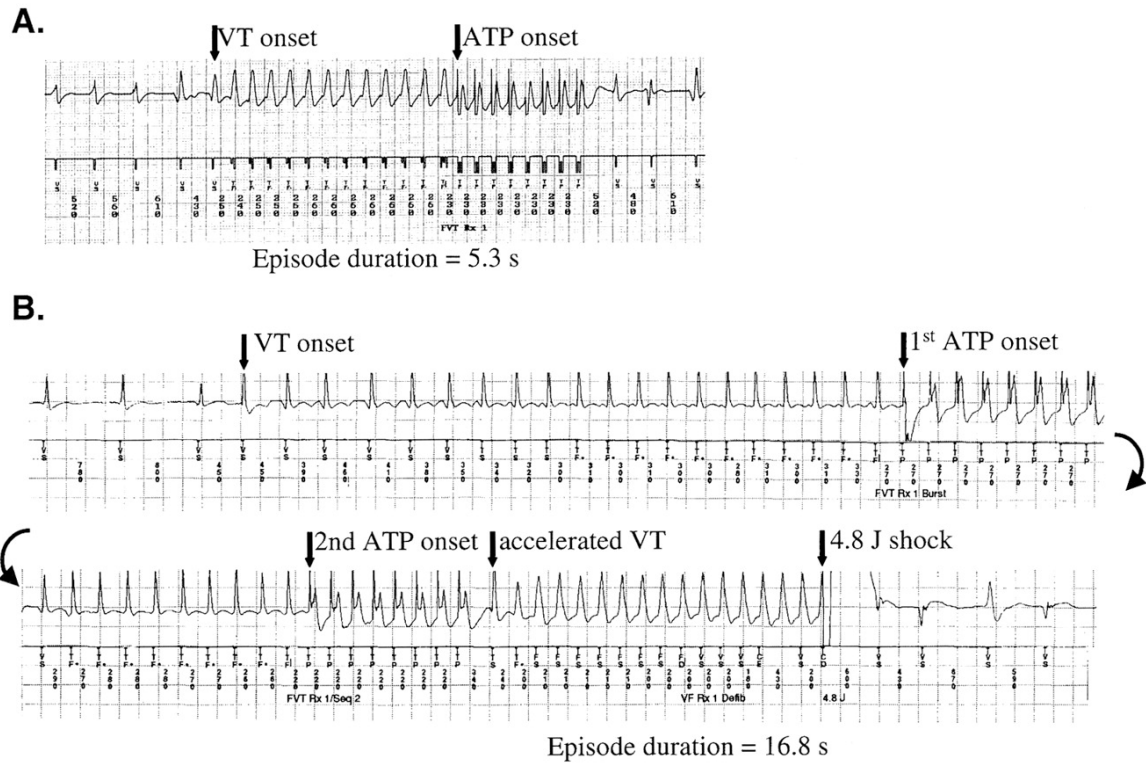
## Defibrillation testing

Further questions to ask:

Salient points:



*Figure 2.1.* Drawing of a man with an implantable cardioverter defibrillator (ICD) and a heart with lead placement and ICD. Adapted from “Implantable Cardioverter-Defibrillators,” by J.M. Torpy, C. Lynn, and R.M. Glass, 2007, *JAMA*, 297, p. 1946. Copyright 2007 by the American Medical Association. Reprinted with permission.



*Figure 2.2.* Example of ventricular tachycardia being terminated by antitachycardia pacing (A). Example of failed antitachycardia pacing accelerating ventricular tachycardia followed by shock termination (B). Adapted from “Shock reduction using antitachycardia pacing for spontaneous rapid ventricular tachycardia in patients with coronary artery disease,” by M. S. Wathen et. al. 2001. *Circulation*, 104, 796-801. Copyright 2001 by Wolters Kluwer Health. Reprinted with permission.





*Figure 2.3.* Example of an ICD computer programmer used to retrieve stored data and electrograms, test atrial and ventricular leads, and program pacing and antitachycardia therapy parameters. Reproduced with permission of Medtronic, Inc.

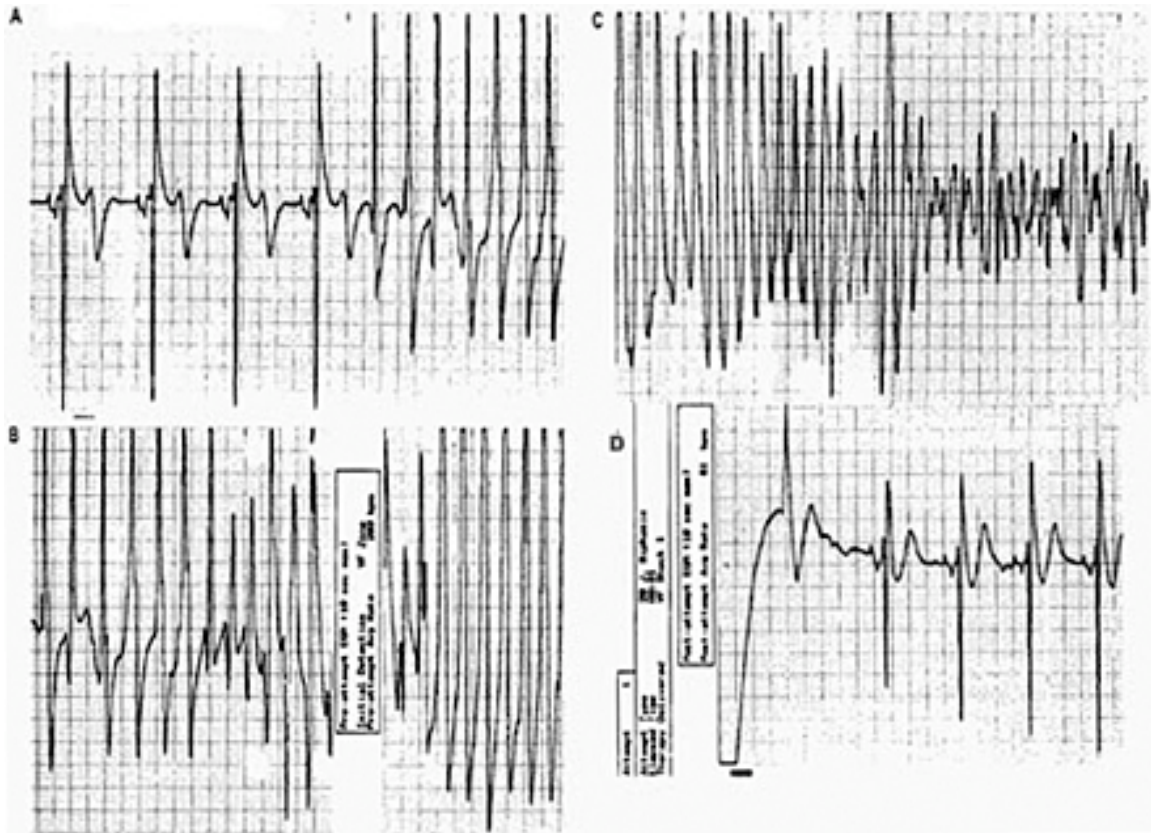


Figure 2.4. Stored ICD electrogram showing ventricular fibrillation being converted to sinus rhythm following a shock. Adapted from “Efficiency of implantable cardioverter-defibrillator for the prevention of sudden death in patients with hypertrophic cardiomyopathy,” by B. J. Maron et. al. 2000. *NEJM*, 342, 365-373. Copyright 2000 by the Massachusetts Medical Society. Reprinted with permission.

## Appendix A: Institutional Review Board Approval



THE UNIVERSITY  
of NORTH CAROLINA  
at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS  
Medical School Building 52  
Mason Farm Road  
CB #7097  
Chapel Hill, NC 27599-7097  
(919) 966-3113  
Web site: [ohre.unc.edu](http://ohre.unc.edu)  
<https://my.research.unc.edu> for IRB status  
Federalwide Assurance (FWA) #4801

To: Karen Jakub  
School of Nursing  
CB: 7460

From: Public Health-Nursing IRB

  
Authorized signature on behalf of IRB

Approval Date: 11/03/2009

Expiration Date of Approval: 11/02/2010

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)

Submission Type: Initial

Expedited Category: 7.Surveys/interviews/focus groups,5.Existing or non-research data,6.Voice/image research recordings

Study #: 09-1870

Study Title: Long-Term Adjustment and Reimplantation Surgery in Patients with Implantable Cardioverter Defibrillators (ICD)

This submission has been approved by the above IRB for the period indicated. It has been determined that the risk involved in this research is no more than minimal.

### Study Description:

Purpose: To examine the (a) long-term physical, psychological and social consequences of living with an implantable cardiac defibrillator (ICD) and (b) the experience of recurrent surgery for patients with ICDs.

Participants: A total of 24 adults with an ICD for at least 4 years; who are at least 22 years of age.

Procedures (methods): Ethnographic methods including participant observation, interviews, and review of medical records.

### Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

When applicable, enclosed are stamped copies of approved consent documents and other

page 1 of 2

recruitment materials. You must copy the stamped consent forms for use with subjects unless you have approval to do otherwise.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented (use the modification form at [ohre.unc.edu/forms](https://ohre.unc.edu/forms)). Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at <https://irbis.unc.edu/irb>.

Researchers are reminded that additional approvals may be needed from relevant "gatekeepers" to access subjects (e.g., principals, facility directors, healthcare system).

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:

Margarete Sandelowski, School Of Nursing

## REFERENCES

- Ågård, A., Löfmark, R., Edvardsson, N., & Ekman, I. (2007). Views of patients with heart failure about their role in the decision to start implantable cardioverter-defibrillator treatment: Prescription rather than participation. *Journal of Medical Ethics*, 33, 514-518. doi: 10.1136/jme.2006.017723
- Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. (1997). A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. *New England Journal of Medicine*, 337, 1576-1583. doi: 10.1056/NEJM199711273372202
- Bardy, G. H., Smith, W. M., Hood, M. A., Crozier, I. G., Melton, I. C., Jordaens, L., . . . Grace, A. A. (2010). An entirely subcutaneous implantable cardioverter-defibrillator. *New England Journal of Medicine*, 363, 36-44. doi: 10.1056/NEJMoa0909545
- Becker, R., Ruf-Richter, J., Senges-Becker, J. C., Bauer, A., Weretka, S., Voss, F., . . . Schoels, W. (2004). Patient alert in implantable cardioverter defibrillators: Toy or tool? *Journal of the American College of Cardiology*, 44, 95-98. doi: 10.1016/j.jacc.2004.03.051
- Braun, T. C., Hagen, N. A., Hatfield, R. E., & Wyse, D. G. (1999). Cardiac pacemakers and implantable defibrillators in terminal care. *Journal of Pain and Symptom Management*, 18(2), 126-131.
- Bristow, M. R., Saxon, L. A., Boehmer, J., Krueger, S., Kass, D. A., DeMarco, T., . . . DiCarlo, L. (2004). Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. *New England Journal of Medicine*, 350, 2140-2150. doi: 10.1056/NEJMoa032423
- Burke, L. J. (1996). Securing life through technology acceptance: The first six months after transvenous internal cardioverter defibrillator implantation. *Heart & Lung*, 25, 352-356. doi: 10.1016/S0147-9563(96)80077-X
- Cannom, D. S., & Prystowsky, E. N. (2004). The evolution of the implantable cardioverter defibrillator. *PACE*, 27, 419-431. doi: 10.1111/j.1540-8159.2004.00457.x
- Carroll, D. L., & Hamilton, G. A. (2005). Quality of life in implanted cardioverter defibrillator recipients: The impact of a device shock. *Heart & Lung*, 34, 169-178. doi: 10.1016/j.hrtlng.2004.10.002
- Carroll, D. L., & Hamilton, G. A. (2008). Long-term effects of implanted cardioverter-defibrillators on health status, quality of life, and psychological state. *American Journal of Critical Care*, 17, 222-230.

- Carroll, D. L., Hamilton, G. A., & Kenney, B. J. (2002). Changes in health status, psychological distress, and quality of life in implantable cardioverter defibrillator recipients between 6 months and 1 year after implantation. *European Journal of Cardiovascular Nursing*, 1, 213-219. doi: 10.1016/S1474-5151(02)00040-3
- Cassagneau, R., Ploux, S., Ritter, P., Jan, E., Barandon, L., Deplagne, A., . . . Bordachar, P. (2001). Long-term outcomes after pocket or scar revision and reimplantation of pacemakers with preerosion. *PACE*, 34, 150-154. doi: 10.1111/j.1540-8159.2010.02950.x
- Charmaz, K. (1987). Struggling for a self: Identity levels of the chronically ill. In J. Roth & P. Conrad (Eds.), *Research in the Sociology of Health Care* (Vol. 6, *The Experience and Management of Chronic Illness*, pp. 283-321). Greenwich, CT: JAI Press.
- Charmaz, K. (1995). Identity dilemmas of chronically ill men. In D. Sabo & D. F. Gordon (Eds.), *Men's health and illness: Gender, power and body* (pp. 266-291). Thousand Oaks, CA: Sage.
- Connell, R. W. (2005). *Masculinities* (2 ed.). Berkeley and Los Angeles, CA: University of California Press.
- Cordeiro, P. G. (2008). Breast reconstruction after surgery for breast cancer. *New England Journal of Medicine*, 359, 1590-1601. doi:10.1056/NEJMct0802899
- Courtenay, W. H. (2000). Constructions of masculinity and their influence on men's well-being: A theory of gender and health. *Social Science & Medicine*, 50, 1385-1401. doi: 10.1016/S0277-9536(99)00390-1
- Crössmann, A., Pauli, P., Dengler, W., Kühlkamp, V., & Wiedemann, G. (2007). Stability and cause of anxiety in patients with an implantable cardioverter defibrillator: A longitudinal two year follow-up. *Heart & Lung*, 36, 87-95. doi: 10.1016/j.hrtlng.2006.08.001
- Dickerson, S. S. (2002). Redefining life while forestalling death: Living with an implantable cardioverter defibrillator after a sudden cardiac death experience. *Qualitative Health Research*, 12, 360-372. doi: 10.1177/104973202129119946
- Dickerson, S. S. (2005). Technology-patient interactions: Internet use for gaining a healthy context for living with an implantable cardioverter defibrillator. *Heart & Lung*, 34, 157-168. doi: 10.1016/j.hrtlng.2004.08.004
- Dougherty, C. M. (1995). Psychological reactions and family adjustment in shock versus no shock groups after implantation of internal cardioverter defibrillator. *Heart & Lung*, 24, 281-291.

- Dougherty, C. M., Benoliel, J. Q., & Bellin, C. (2000). Domains of nursing intervention after sudden cardiac arrest and automatic internal cardioverter defibrillator implantation. *Heart & Lung, 29*, 79-86. doi: 10.1016/S0147-9563(00)90002-5
- Dougherty, C. M., Thompson, E. A., & Lewis, F. M. (2005). Long-term outcomes of a telephone intervention after an ICD. *PACE, 28*, 1157-1167. doi: 10.1111/j.1540-8159.2005.09500.x
- Dubin, A. M., Batsford, W. P., Lewis, R. J., & Rosenfeld, L. E. (1996). Quality-of-life in patients receiving implantable cardioverter defibrillators at or before age 40. *PACE, 19*, 1555-1559. doi: 10.1111/j.1540-8159.1996.tb03180.x
- Dunbar, S. B. (2005). Psychosocial issues of patients with implantable cardioverter defibrillators. *American Journal of Critical Care, 14*, 294-303.
- Dunbar, S. B., Langberg, J. J., Reilly, C. M., Viswanathan, B., McCarty, F., Culler, S. D., . . . Weintraub, W. S. (2009). Effect of a psychoeducational intervention on depression, anxiety, and health resource use in implantable cardioverter defibrillator patients. *PACE, 32*, 1259-1271. doi: 10.1111/j.1540-8159.2009.02495.x
- Dunbar, S. B., Warner, C. D., & Purcell, J. A. (1993). Internal cardioverter defibrillator device discharge: Experiences of patients and family members. *Heart & Lung, 22*, 494-501.
- Eckstein, J., Koller, M. T., Zabel, M., Kalusche, D., Schaer, B. A., Osswald, S., & Sticherling, C. (2008). Necessity for surgical revision of defibrillator leads implanted long-term: Causes and management. *Circulation, 117*, 2727-2733. doi: 10.1161/CIRCULATIONAHA.107.740670
- Edelman, S., Lemon, J., & Kidman, A. (2003). Psychological therapies for recipients of implantable cardioverter defibrillators. *Heart & Lung, 32*, 234-240.
- Elder, G. H. (1994). Time, human agency, and social change: Perspectives on the life course. *Social Psychology Quarterly, 57*, 4-15.
- Elder, G. H., & Johnson, M. K. (2003). The life course and aging: Challenges, lessons, and new directions. In R. A. Settersten (Ed.), *Invitation to the life course: Toward new understandings of later life* (pp. 49-81). Amityville, NY: Baywood.
- Ellinor, P. T., Guy, M. L., Ruskin, J. N., & McGovern, B. A. (2003). Variability in implantable cardioverter defibrillator pulse generator longevity between manufacturers. *PACE, 26 (Pt. 1)*, 71-75. doi: 10.1046/j.1460-9592.2003.00153.x
- Emerson, R. M., Fretz, R. I., & Shaw, L. K. (1995). *Writing ethnographic fieldnotes*. Chicago: University of Chicago Press.

- Flemme, I., Edvardsson, N., Hinic, H., Jinhage, B.-M., Dalman, M., & Fridlund, B. (2005). Long-term quality of life and uncertainty in patients living with an implantable cardioverter defibrillator. *Heart & Lung, 34*, 386-392. doi: 10.1016/j.hrtlng.2005.05.003
- Gauri, A. J., Davis, A., Hong, T., Burke, M. C., & Knight, B. P. (2006). Disparities in the use of primary prevention and defibrillator therapy among blacks and women. *American Journal of Medicine, 119*, 167.e117-167.e121.
- Gehi, A. K., Mehta, D., & Gomes, J. A. (2006). Evaluation and management of patients after implantable cardioverter-defibrillator shock. *JAMA, 296*, 2839-2847. doi: 10.1001/jama.296.23.2839
- Geist, M., Newman, D., Greene, M., Paquette, M., & Dorian, P., (2000). Permanent explantation of implantable cardioverter defibrillators. *PACE, 23*, 2024-2029. doi: 10.1111/j.1540-8159.2000.tb00771.x
- Gepner, K., Przybylski, A., Maciąg, A., Sterliński, M., Lewandowski, M., Syska, P., . . . Szwed, H. (2007). Causes of redo procedures in patients with an implantable cardioverter-defibrillator: Long-term follow-up results. *Kardiologia Polska, 65*, 893-898.
- Goldstein, N., Mehta, D., Siddiqui, S., Teitelbaum, E., Zeidman, J., Singson, M., . . . Morrison, R. S. (2008). "That's like an act of suicide" Patient attitudes toward deactivation of implantable defibrillators. *Journal of General Internal Medicine, 23* (Supplement 1), 7-12. doi: 10.1007/s11606-007-0239-8
- Goodman, M., & Hess, B. (1999). Could implantable cardioverter defibrillators provide a human model supporting the learned helplessness theory of depression? *General Hospital Psychiatry, 21*, 282-285. doi: 10.1016/S0163-8343(99)00030-4
- Goossens, G. A., Vrebos, M., Stas, M., Wever, I. D., & Frederickx, L. (2005). Central vascular access devices in oncology and hematology considered from a different point of view: How do patients experience their vascular access ports. *Journal of Infusion, 28*, 61-67. doi:10.1097/00129804-200501000-00008
- Groeneveld, P. W., Heidenreich, P. A., & Garber, A. M. (2005). Trends in implantable cardioverter-defibrillator racial disparity: The importance of geography. *Journal of the American College of Cardiology, 45*(1), 72-78.
- Hamilton, G. A., & Carroll, D. L. (2003). The effects of age on quality of life in implantable cardioverter defibrillator recipients. *Journal of Clinical Nursing, 13*, 194-200.



- Hauser, R. G., Hayes, D. L., Epstein, A. E., Cannom, D. S., Vlay, S. C., Song, S. L., & Tyers, F. O. (2006). Multicenter experience with failed and recalled implantable cardioverter-defibrillator pulse generators. *Heart Rhythm*, 3, 640-644. doi: 10.1016/j.hrthm.2006.02.011
- Hegel, M. T., Griegel, L. E., Black, C., & Goulden, L. (1997). Anxiety and depression in patients receiving implanted cardioverter-defibrillators: A longitudinal investigation. *International Journal of Psychiatry in Medicine*, 27, 57-69. doi: 10.2190/1G9V-EQMD-MTLQ-E0BW
- Heller, S. S., Ormont, M. A., Lidagoster, L., Sciacca, R., & Steinberg, J. S. (1998). Psychosocial outcome after ICD implantation. *PACE*, 21, 1207-1215. doi: 10.1111/j.1540-8159.1998.tb00179.x
- Joachim, G., & Acorn, S. (2000). Living with chronic illness: The interface of stigma and normalization. *Canadian Journal of Nursing Research*, 32, 37-48.
- Jung, W., Rillig, A., Birkemeyer, P., Miljak, T., & Meyerfeldt, U. (2008). Advances in remote monitoring of implantable pacemakers, cardioverter defibrillators and cardiac resynchronization therapy systems. *Journal of Interventional Cardiac Electrophysiology*, 23, 73-85. doi: 10.1007/s10840-008-9311-5
- Kaufman, S. R., Mueller, P. S., Ottenberg, A. L., & Koenig, B. A. (2011). Ironic technology: Old age and the implantable cardioverter defibrillator in US health care. *Social Science & Medicine*, 72, 6-14. doi: 10.1016/j.socscimed.2010.09.052
- Kellehear, A. (1990). The near-death experience as a status passage. *Social Science & Medicine*, 31, 933-939. doi: 10.1016/0277-9536(90)90033-O
- Kleemann, T., Becker, T., Doenges, K., Vater, M., Senges, J., Schneider, S., . . . Seidl, K. (2007). Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. *Circulation*, 115, 2474-2480. doi: 10.1161/CIRCULATIONAHA.106.663807
- Kowalski, M., Huizar, J. F., Kaszala, K., & Wood, M. (2008). Problems with implantable cardiac device therapy. *Cardiology Clinics*, 26, 441-458. doi: 10.1016/j.ccl.2008.03.012
- Kundrat, A. L., & Nussbaum, J. F. (2003). The impact of invisible illness on identity and contextual age across the life span. *Health Communication*, 15, 331-347. doi: 10.1207/S15327027HC1503\_5
- Lemon, J., Edelman, S., & Kirkness, A. (2004). Avoidance behaviors in patients with implantable cardioverter defibrillators. *Heart & Lung*, 33, 176-182. doi: 10.1016/j.hrtlng.2004.02.005

- Li, H., Natale, A., Zhu, W., Greenfield, R. A., Easley, A., Barrington, W., & Windle, J. (1998). Causes and consequences of discontinuation of the implantable cardioverter-defibrillator therapy in non-terminally ill patients. *American Journal of Cardiology*, 81, 1203-1205. doi: 10.1016/S0002-9149(98)00090-3
- Li, Y., Bain, L., & Steinberg, A. G., (2004). Parental decision-making in considering cochlear implant technology for a deaf child. *International Journal of Pediatric Otorhinolaryngology*, 68, 1027-1038. doi: 10.1016/j.ijporl.2004.03.010
- Luyster, F. S., Hughes, J. W., Waechter, D., & Joseph, R. (2006). Resource loss predicts depression and anxiety among patients treated with an implantable cardioverter defibrillator. *Psychosomatic Medicine*, 68, 794-800. doi: 10.1097/01.psy.0000227722.92307.35
- Matthews, C. K., & Harrington, N. G. (2000). Invisible disability. In D. O. Braithwaite & T. L. Thompson (Eds.), *Handbook of communication and people with disabilities: Research and application* (pp. 405-421). Mahwah, NJ: Lawrence Erlbaum Associates.
- Maxwell, J. A. (2002). Understanding and validity in qualitative research. In A. M. Huberman & M. B. Miles (Eds.), *The qualitative researcher's companion* (pp. 37-64). Thousand Oaks, CA: Sage.
- Miles, M. B., & Huberman, A. M. (1994). *Qualitative data analysis: An expanded sourcebook* (2nd ed.). Thousand Oaks, CA: Sage.
- Moss, A. J., Hall, J., Cannom, D. S., Daubert, J. P., Higgins, S. L., Klein, H., . . . Heo, M. (1996). Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. *New England Journal of Medicine*, 335, 1933-1940. doi: 10.1056/NEJM199612263352601
- Moss, A. J., Zarebr, W., Hall, J., Klein, H., Wilber, D. J., Cannom, D. S., . . . Andrews, M. L. (2002). Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *New England Journal of Medicine*, 346(12), 877-883. doi: 10.1056/NEJMoa013474
- Pachulski, R. T., Adkins, D. C., & Mirza, H. (2001). Conscious sedation with intermittent Midazolam and Fentanyl in electrophysiology procedures. *Journal of Interventional Cardiology*, 14, 143-146.
- Paterson, B. L. (2001). The shifting perspectives model of chronic illness. *Journal of Nursing Scholarship*, 33, 21-26. doi: 10.1111/j.1547-5069.2001.00021.x
- Patton, M. Q. (2002). *Qualitative research and evaluation methods* (3 ed.). Thousand Oaks, CA: Sage.

- Pauli, P., Wiedemann, G., Dengler, W., Blaumann-Benninghoff, G., & Köhlkamp, V. (1999). Anxiety in patients with an automatic implantable cardioverter defibrillator: What differentiates them from panic patients? . *Psychosomatic Medicine*, *61*, 69-76.
- Prudente, L., Reigle, J., Bourguignon, C., Haines, D. E., & DiMarco, J. P. (2006). Psychological indices and phantom shocks in patients with ICD. *Journal of Interventional Cardiac Electrophysiology*, *15*, 185-190. doi: 10.1007/s10840-006-9010-z
- Robertson, S. (2007). *Understanding men and health*. Berkshire, England: Open University Press.
- Rogers, B. L., & Cowles, K. V. (1993). The qualitative research audit trail: A complex collection of documentation. *Research in Nursing & Health*, *16*, 216-226.
- Sandelowski, M. (1995a). Qualitative analysis: What it is and how to begin. *Research in Nursing & Health*, *18*, 371-375. doi: 10.1002/nur.4770180411
- Sandelowski, M. (1995b). Sample size in qualitative research. *Research in Nursing & Health*, *18*, 179-183.
- Schoenfeld, M. H. (2000). Deciding against defibrillator replacement: Second-guessing the past? *PACE*, *23*, 2019-2021.
- Schron, E., Exner, D., Yao, Q., Jenkins, L. S., Steinberg, J. S., Cook, J., . . . investigators, A. (2002). Quality of life in the antiarrhythmics versus implantable defibrillators trial: Impact of therapy and influence of adverse symptoms and defibrillator shocks. *Circulation*, *105*, 589-594.
- Sears, S. F., & Conti, J. B. (2002). Quality of life and psychological functioning of ICD patients. *Heart* 2002, 488-493.
- Sears, S. F., & Conti, J. B. (2006). Psychological aspects of cardiac devices and recalls in patients with implantable cardioverter defibrillators. *American Journal of Cardiology*, *98*, 565-567.
- Sears, S. F., Conti, J. B., Curtis, A., Saia, T. L., Foote, R., & Wen, F. (1999). Affective distress and implantable cardioverter defibrillators: Cases for psychological and behavioral interventions. *PACE*, *22*, 1831-1834. doi: 10.1111/j.1540-8159.1999.tb00422.x
- Sears, S. F., Todaro, J. F., Lewis, T. S., Sotile, W., & Conti, J. B. (1999). Examining the psychosocial impact of implantable cardioverter defibrillators: A literature review. *Clinical Cardiology*, *22*, 481-489.

- Sherrid, M. V., & Daubert, J. P. (2008). Risks and challenges of implantable cardioverter-defibrillators in young adults. *Progress in Cardiovascular Diseases*, 51, 237-263. doi: 10.1016/j.pcad.2008.10.001
- Shim, J. K., Russ, A. J., & Kaufman, S. R. (2006). Risk, life extension and the pursuit of medical possibility. *Sociology of Health & Illness*, 28, 479-502. doi: 10.1111/j.1467-9566.2006.00502.x
- Smith, G., Dunbar, S. B., Valderrama, A. L., & Viswanathan, B. (2006). Gender differences in implantable cardioverter-defibrillator patients at time of insertion. *Progress in Cardiovascular Nursing*, 21, 76-82. doi: 10.1111/j.0889-7204.2006.04843.x
- Sowell, L. V., Kuhl, E. A., Sears, S. F., Klodell, C. T., & Conti, J. B. (2006). Device implant technique and consideration of body image: Specific procedures for implantable cardioverter defibrillators in female patients. *Journal of Women's Health*, 15(7), 830-835. doi: 10.1089/jwh.2006.15.830
- Sowell, L. V., Sears, S. F., Walker, R. L., Kuhl, E. A., & Conti, J. B. (2007). Anxiety and marital adjustment in patients with implantable cardioverter defibrillator and their spouses. *Journal of Cardiopulmonary Rehabilitation and Prevention*, 27, 46-49.
- Sowell, R. L., Phillips, K. D., Seals, B. F., Misener, T. R., & Rush, C. (2001). HIV-Infected women's experiences and beliefs related to AZT therapy during pregnancy. *AIDS Patient Care and STDs*, 15, 201-209.
- Spradley, J. P. (1979). *The ethnographic interview*. Belmont, CA: Wadsworth.
- Spradley, J. P. (1980). *Participant observation*. Belmont, CA: Wadsworth/Thompson Learning.
- Stanley, A., DeLia, D., & Cantor, J. C. (2007). Racial disparity and technology diffusion: The case of cardioverter defibrillator implants, 1996-2001. *Journal of the National Medical Association*, 99(3), 201-207.
- Steinke, E. E., Gill-Hopple, K., Valdez, D., & Wooster, M. (2005). Sexual concerns and educational needs after an implantable cardioverter defibrillator. *Heart & Lung*, 34(5), 299-208. doi: 10.1016/j.hrtlng.2005.03.002
- Stevenson, W. G., Chaitman, B. R., Ellenbogen, K. A., Epstein, A. E., Gross, W. L., Hayes, D. L., . . . Sweeney, M. O. (2004). Clinical assessment and management of patients with implantable cardioverter-defibrillators presenting to nonelectrophysiologists. *Circulation*, 110, 3866-3869. doi: 10.1161/01.CIR.0000149716.03295.7C

- Stewart, G. C., Weintraub, J. R., Pratibhu, P. P., Semigran, M. J., Camuso, J. M., Brooks, K., . . . Stevenson, L. W. (2010). Patient expectations from implantable defibrillators to prevent death in heart failure. *Journal of Cardiac Failure, 16*, 106-113. doi: 10.1016/j.cardfail.2009.09.003
- Sulik, G. A. (2007). The balancing act: Care work of the self and coping with breast cancer. *Gender and Society, 21*, 857-877. doi: 10.1177/0891243207309898
- Sulmasy, D. P. (2007). Within you/ without you: Biotechnology, ontology, and ethics. *Journal of General Internal Medicine, 23 (Suppl 1)*, 69-72.
- Undavia, M., Goldstein, N., Cohen, P., Sinthawananarong, K., Singson, M., Bhutani, D., . . . Mehta, D. (2008). Impact of implantable cardioverter-defibrillator recalls on patients' anxiety, depression, and quality of life. *PACE, 31*, 1411-1418. doi: 10.1111/j.1540-8159.2008.01204.x
- van den Broek, K., Denollet, J., Nyklicek, I., & van der Voort, P. (2006). Psychological reaction to potential malfunctioning of implantable defibrillator. *PACE, 29*, 953-956. doi: 10.1111/j.1540-8159.2006.00468.x
- Vazquez, L., Kuhl, E. A., Shea, J. B., Kirkness, A., Lemon, J., Whalley, D., . . . Sears, S. F. (2008). Age-specific differences in women with implantable cardioverter defibrillators: An international multi center study. *PACE, 31*, 1528-1534. doi: 10.1111/j.1540-8159.2008.01223.x
- Wallace, R. L., Sears, S. F., Lewis, T. S., Griffiths, J. T., Curtis, A. B., & Conti, J. B. (2002). Predictors of quality of life in long-term recipients of implantable cardioverter defibrillators. *Journal of Cardiopulmonary Rehabilitation, 22*, 278-281.
- Weston, J. M., Norris, E. V., & Clark, E. M. (2011). The invisible disease: Making sense of an osteoporosis diagnosis in older age. *Qualitative Health Research, 21*, 1692. doi: 10.1177/1049732311416825
- Wild, D. M., Fisher, J. D., Kim, S. G., Ferrick, K. J., Gross, J. N., & Palma, E. C. (2004). Pacemakers and implantable cardioverter defibrillators: Device longevity is more important than smaller size: The patient's viewpoint. *PACE, 27*, 1526-1529. doi: 10.1111/j.1540-8159.2004.00671.x
- Wilkoff, B. L., Auricchio, A., Brugada, J., Cowie, M., Ellenbogen, K. A., Gillis, A. M., . . . Love, C. L. (2008). HRS/EHRA expert consensus on monitoring of cardiovascular implantable electronic devices: description of techniques, indications, personnel, frequency and ethical considerations. *Europace, 5*, 707-725. doi: 10.1093/europace/eun122

Williams, A. M., Young, J., Nikoletti, S., & McRae, S. (2007). Getting on with life: Accepting the permanency of an implantable cardioverter defibrillator. *International Journal of Nursing Practice*, 13, 166-172.